Scope and Standards of Practice: Clinical Research Nursing

International Association of Clinical Research Nurses

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Contents

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Scope of Clinical Research Nursing

Nurses are practicing as clinical research nurses (CRN) worldwide. The global landscape for clinical research has changed dramatically in the past 10 years. Ninety-five percent of all countries have participated in clinical trials and are represented in the Clinicaltrials.gov database (Richter, 2014). It is estimated that more than 2.3 million volunteers completed participation in a US clinical research study in 2013 (CISCRP.org). Currently, 17,210 clinical trials registered with Clinicaltrials.gov are open to recruitment in the US (Clinicaltrials.gov, n.d.). In addition, participants are actively engaged in many more US trials that are not open to recruitment. Both healthy people and those with health conditions have volunteered their time and their subjective and objective data to help advance health sciences. Often these volunteers step outside the mainstream of clinical care, known as the "standard of care," and are willing to give of themselves by participating in clinical research. The best interest of the volunteer, along with the integrity of the protocol, is the primary focus of the CRN. Persons who volunteer to participate in clinical research deserve expert nursing care that ensures high-quality, ethical, safe care yielding high-quality data. The care of the research volunteer must be consistent with the research plan, care protocol, and clinical need.

Through specialty practice, the CRN makes important contributions to the clinical research process, contributing to positive outcomes affecting the quality of the research and the participant's safety.The participant's care and the research process are closely related, requiring the CRN nto continually balance the clinical needs of the participant and the requirements of the research. The ability to achieve and maintain this balance is imperative for high-quality outcomes in the clinical research enterprise. . CRNs must demonstrate expert clinical skills; show well-developed critical thinking skills; and practice knowledge of regulatory, ethical, and scientific aspects of clinical research. CRNs are members of interdisciplinary teams that involve participants, their families, physicians, researchers, and other specialists. The CRN provides a consistent participant focus in the midst of managing research protocols

Studies in which CRNs work range from behavioral studies to first-in-human trials. CRNs are often the first to care for participants involved in a clinical trial assessing new therapeutics or devices. Observations made by CRNs potentially affect the future of the therapeutic/device development or time to market, as well as the appropriate nursing actions and safety profiles for novel therapeutics or devices. CRNs working in this area of research must observe participants closely and advocate for safety in an absence of established guidelines.

CRNs care for a wide range of participants, from healthy volunteers to critically ill patients, in a variety of settings, from the community to critical care units. CRNs care for participants young to old from every practice specialty, for example cardiology, oncology,

nephrology, and gastroenterology. Practice as a CRN requires a unique body of knowledge consisting of specialized training in nursing care, research regulations, scientific process, data collection, analysis, and interpretation.

CRN specialty practice incorporates the five domains of practice displayed in Figure 1. The domains of 1) human subject protection; 2) care coordination and continuity; 3) contributing to the science; 4) clinical practice; and 5) study management provide a framework for CRN practice regardless of the role or setting. Consensus on these dimensions and related role activities was reached through a national expert panel that participated in a Delphi survey (Castro et al., 2011).

Figure 1. Domains of Clinical Research Nursing Practice

Adapted from U.S. Department of Health and Human Services, 2009

Definition of Clinical Research Nursing

Clinical research nursing is the specialized practice of professional nursing focused on maintaining equilibrium between care of the research participant and fidelity to the research protocol. This specialty practice incorporates human subjects protection; care coordination and continuity; contribution to clinical science; clinical practice; and study management throughout a variety of professional roles, practice settings, and clinical specialties (IACRN, 2012).

Differentiation of Clinical Research Nurse from Nurse Researcher

It is important to make clear the distinction between a *clinical research nurse (CRN)* and a *nurse researcher*. Although there might be role overlap in certain situations, the term "nurse researcher" refers to a doctorally-prepared nurse who is focused on the contribution of new knowledge to nursing science through leadership in independent research. CRNs, however, contribute to science with a focus on the care and coordination of research participants in a research practice setting (Hastings et al., 2012).

Collateral Definitions

Several additional definitions are important for a complete understanding of the clinical nursing research role. The following definitions provide clarity for concepts discussed in this document and are based on background information from the NIH CenterWatch and standard research knowledge.

Clinical Research is defined as research with human subjects that is:

- Participant-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that use human tissues that cannot be linked to a living individual. It includes:
    - mechanisms of human disease
    - therapeutic interventions
    - clinical trials
    - development of new technologies
- Epidemiological and behavioral studies.
- Outcomes research and health services research.

Clinical Trial: Research involving human subjects that is a controlled investigation of a drug, device, or intervention. These studies are prospective and may be diagnostic or therapeutic in nature.

Participant: A person who volunteers to participate in a research study. A participant may be a

patient, an individual with a chronic or acute medical or mental health condition, or a healthy volunteer.

There are some instances in this document where the terms “subject” and “patient” are used in place of “participant,” when quoting directly from a source or when following document guidelines. It is the intent of the authors that these terms may be used interchangeably. In this document, all three terms refer to a person who volunteers to participate in a research study.

History and Evolution of Clinical Research Nursing

Clinical research is the backbone of international scientific discovery. The use of high-tech procedures, techniques, and laboratories moves discovery quickly from bench to bedside. In the past, physicians were responsible for the day-to-day conduct and management of clinical trials (Fox, 1997). The movement of translational research pushes the speed of discovery and places participants in a position of great benefit but also potential increased risk. The unique skills of the CRN are perfectly suited to foster this rapid discovery while ensuring the protections of the participants. Today, nurses play a key role in the clinical research enterprise (Hastings, 2012).

The CRN’s role and specialized practice have been explored and described in the literature as far back as the 1960s. Early chemotherapy trials, for example, were implemented by a clinical trials nurse (CTN) and it was recognized then that this role was distinct and required a unique set of knowledge and skills in addition to those outlined for all nurses (Deininger, 2008).

Throughout the 1980s and 1990s, the literature continued to expand on the concept of the CRN as a professional and specialty nursing practice (Johnson, 1986; McEvoy, 1991), and the number of clinical trials in subspecialties grew. The CRN role became more complex with an increasing need for definition. Despite the lack of clear role definition, CRNs were considered crucial to the successful conduct of clinical trials (McKinney, 2000). The role of the CRN was largely accepted as a career path for nurses by the 1990s (McEvoy, 1991; Eaton & Pratt, 1990). DiGiulio et al. (1996) described the need to expand the role of nurses in clinical trials.

In 1989, the nurse managers of the General Clinical Research Center (GCRC) programs were, for the first time, invited by the National Institutes of Health (NIH) to participate in the annual GCRC Program Directors two-day conference in Gaithersburg, MD. At this historic meeting, a group of nurse managers volunteered—and were unanimously supported by the program directors—to establish a formal structure for the National Association of GCRC Nurse Managers (GCRCNM). The mission of the association was to exchange knowledge and ideas; to establish nursing standards in the Clinical Research Center settings; and to consult, support, and

advance competencies for the GCRC nurse managers. The outcome of many hours of dedicated individual and regional work included an orientation program for new GCRC nurse managers, preparation guidelines for NIH site visits and Joint Commission reviews, and worksheets and tools for planning nursing services for new protocols. In addition to providing support to the nurse managers, the group worked to set standards for CRN education, training, and research procedures that different settings have in common and address issues of ethical and safe conduct of clinical research. In response to funding changes occurring by the year 2000 and the apparent need to increase support to the growing base of CRNs, the GCRCNM group expanded their assistance to CRNs working inside and outside of clinical research centers.

In 2003, the NIH accelerated the need for specially skilled CRNs with the implementation of the NIH Roadmap (Zerhouni, 2003). With the push of research moving rapidly from bench to bedside, studies were becoming more complex and multi-institutional. Focus shifted from research conducted at centralized research centers to research implemented throughout the health care industry and community. Exploring new ways to speed implementation of clinical trials led to an intense period of growth of the specialty practice in all clinical research areas.

During this same period of time, several major international groups began serious efforts to define CRN roles and competencies. The next five years saw many major advances in defining the specialty.

A work group of the Oncology Nursing Society (ONS) began work on the role definition of the CTN in oncology clinical trials. The ONS Clinical Trials Nursing Special Interest Group developed the Clinical Trials Nursing Questionnaire (CTNQ) as a reliable tool for assessment of the research nurse role (Ehrenberger & Lillington, 2004) and the Manual for Clinical Trials Nurses (Klimaszewski, Bacon, Deininger, 2008). The CTNQ has been found a valid and reliable tool in countries throughout the world (Catanina, 2008; Nagel, 2010; Catanina et al., 2011). Although a valuable resource for role definition, the CTNQ did not include the broader role of clinical research nursing that encompassed work outside of oncology clinical trials.

The National General Clinical Research Nurse Manager Association put forth a position statement on clinical research nursing (NGCRNMA, 2006). The position statement was aimed to describe the unique role of the CRN based on the opinions of nursing leaders in the field.

A workgroup of the Royal College of Nursing, the National Institute of Health Research UK Clinical Research Facility Network (NIHR UKCRF Network), and the National Cancer Research Network developed a CRN competency framework to support the specialty for Clinical Research Nurses. This would be the first time a national organizations supported efforts to standardizaton the framework for this speciality (Royal College of Nursing, 2008). In 2009, a

group of seven nurse managers of clinical research units throughout the United States organized the International Association of Clinical Research Nurses (IACRN) and held the first international meeting. In 2010, the NIH Clinical Center nursing department joined with IACRN for the first joint conference, "CRN2010." This conference became the largest organized effort to share results of work done surrounding CRN domains of practice and role delineation (Bevans et al., 2011; Castro et al., 2011).

In 2012, the landmark document *Clinical Research Nursing: A Critical Resource in the National Research Enterprise* was published (Hastings et al., 2012). This work, developed over several years by a taskforce of CRN experts from around the country, summarized growth of this specialty practice and outlined future trends and next steps for further work within the specialty. Key research was simultaneously being done to define the domains of clinical research nursing practice. Agreement from experts was obtained via a Delphi questionnaire approach, resulting in the articulation of the five domains of practice (Figure 1) that continue to guide the specialty practice (Castro et al., 2011).

The expansion of clinical research has resulted in a clear need for nurses specializing in clinical research practice to best meet the needs of the research participant, adhere to research protocol requirements, and maintain research standards to achieve meaningful results. Over the last 50 years, nurses working in clinical research have moved from a supportive role to an essential player in the clinical research enterprise.

Prevalence of Clinical Research Nurses

CRNs practice in all venues of the current clinical research enterprise including federal, academic, industry, and private research, as well as non-research-focused settings (Hastings et al., 2012). Publications as early as 1991 report nurses as the largest workforce supporting the day-to-day operations of clinical research, as designated by clinical research investigators (Mueller, 2001). Given this, it is reasonable to suggest that nurses have been a driving force in the conduct and completion of the 197,314 trials in 190 countries around the world registered on Clinicaltrials.gov since its inception in 2000.

Quantifying the number of nurses in this workforce is challenging for several reasons. One is the number of different titles that are associated with clinical research nursing roles in various settings and in the literature. Another is the number and variety of non-traditional settings that employ nurses in clinical research. Finally, clinical research nursing practice is evolving in countries such as China and South Africa. The following data has been collected through conversation with CRN leaders throughout the world.

According to data from the Clinical Center Nurse Credentialing Office, there are currently 1040 nurses employed by the Clinical Center and Institutes and credentialed to provide clinical research care (C. Hastings, personal communication, October 9, 2015). Managers of 34 research units that are currently or have in the past received federal subsidy for their units report employing 403 CRNs. One center reported 100 other known research nurses outside of their clinical research unit. Similarly, others report additional nurses working in their institutions but are unclear of numbers. These numbers represent a subset of nurses who care for clinical trial participants in the academic setting. Over the past 5 years the Association of Clinical Research Professionals (ACRP; 2009, 2010, 2011, 2012) reports certifying 500 nurses employed in industry and private institutions as Clinical Research Coordinators and Clinical Research Associates. The ONS Clinical Trials Nurses (CTN) Special Interest Group has more than 1,600 members who require a unique framework of knowledge for working with participants involved in clinical research trials. This group is only a subsection of the 35,000 national and international ONS members who identify eligible research participants and support those on clinical trials (Association of Clinical Research Professionals, 2009, 2010, 2011, 2012). Likewise, other nursing specialties such as cardiology, cardiovascular surgery, and rheumatology are anticipated to have a similar number of nurses practicing in clinical research. Outside of academia and federally funded centers, there are clinical research nurses working for industry, private research practices, and regulatory bodies. The number within those settings is yet to be identified; however, it is estimated in the thousands.

Prevalence of clinical research nurses in other countries is also difficult to determine. The National Institute for Health Research Clinical Research Network in the UK reports supporting over 4,207 CRNs throughout its research enterprise, although the numbers are estimated to be almost 10,000 CRNs in the UK. Scotland has identified 600 CRNs, which constitutes approximately 0.5% of the total nursing workforce.

As IACRN becomes known internationally, CRNs from Canada, Japan, China, South Africa, Spain, Switzerland, Holland, and others are coming forward to identify with the specialty practice. IACRN recently provided education in China to more than 300 CRNs, a group that was identified by the organizers as a small fraction of Chinese nurses working in clinical research.

The IACRN continues to collect data on the number of CRNs internationally. It is clear that clinical research nurses are represented in large numbers in academic, industry, and private settings nationally and internationally.

Populations Served

Persons of all ages are recruited to participate in research. Clinical research nurses have expertise in caring for specific groups of participants on the developmental spectrum from

neonates to the elderly. An essential component of the CRN specialty practice is the ability to care for the breadth and depth of the unique needs of those participating in research in any health condition or developmental stage. Participants may be at home, in the community, in a clinic, a group developmental setting, or a health care facility. Participants enter research through a variety of venues that include academic medical centers, community or government facilities, private or community health care organizations, or through an industrial setting.

Two overarching concepts of particular importance to CRNs are participant risk and vulnerability. Participant exposure to risk related to study participation ranges from minimal to high, depending on the condition of the participant and the research intervention. Assessment of risk related to research participation is an essential aspect of the nursing process for all populations.

Vulnerability of patient groups is also an important consideration in clinical research. Members of any population may be considered vulnerable due to cognitive, institutional, medical, economic, or social variables. These vulnerabilities need attention throughout the implementation of the research protocol. Thus, ongoing assessment for risk and vulnerability is central to all clinical research nursing practice.

Pediatric

Children of all ages participate in all types and phases of research. Pediatric participants typically have an acute or chronic condition that requires interface with the health care system. They are often at physical, psychological, or developmental risk due to the physical environment. It is not common for healthy pediatric volunteers to participate in research beyond observational studies. As a highly vulnerable population, children participating in clinical research are afforded additional human subjects protection.

Adult

Adults participating in research encompass a broad spectrum of the population, ranging from healthy volunteers with no preexisting medical conditions to those with specific health conditions or clinical diagnoses. Included in this spectrum is a segment of the population defined, by the Code of Federal Regulations, as “vulnerable populations.” Adults who are considered vulnerable include those who are mentally disabled, economically or educationally disadvantaged, pregnant, women, or prisoners (Public Welfare of Human Subjects, 2015). As in the pediatric population, those designated as vulnerable are afforded additional human subjects protection. Healthy volunteers are most common in the adult study population. They would not otherwise be in the health care system if not for their participation in a clinical research study. They often serve as a control but may also be exposed to risk as a result of their participation. These healthy volunteers, sometimes referred to as “normal volunteers,” may

receive medications or have interventions performed. Despite the designation of "healthy volunteer," this group may incur risk as a result of research participation and are entitled to the same protections as all other research participants. Monitoring this population requires a keen awareness of changes in order to defend against a decline in their health as a result of participation in research.

Elderly

Individual in advanced older age are a unique component of the adult population participating in research. Older persons are frequently underrepresented in research investigations (Elskamp, Hartholt, Patka, Beeck, & van der Cammen, 2012; Hutchins, Unger, Crowley, Coltman, & Albain, 1999). The CRN understands and considers the additional vulnerabilities that may limit elder participation, interfere with compliance, or complicate their participation. This group is often restricted by conditions of frailty, cognition, polypharmacy, and co-morbid conditions (Cox, Kloseck, Crilly, McWilliam, & Diachun, 2011). Financial and transportation limitations unrelated to the research itself may also hinder full participation. The CRN applies knowledge of these limitations to advocate for safety of participants while protecting research efficacy. The CRN is aware that efforts to mitigate these limitations, if appropriate for the specific research study, may allow this segment of the population an opportunity to make important contributions to science and add to the body of knowledge for this age group. "Targeting specific strategies to the condition, site, and population of interest and anticipating potential problems and promptly employing predeveloped contingency plans are key to effective recruitment and retention strategies" (Mody, et al., 2008 p. 2340).

Clinical Research Nurse Practice Environments

CRNs engage participants in the research process throughout the health care continuum and in a variety of settings. Some of the common settings where CRNs practice include private, public, and academic hospitals; physician practices within the community; privately-owned research centers; and Special Care Facilities. They may also practice in less traditional settings such as pharmaceutical offices, academic institutions, government agencies, and clinical research management organizations. The opportunities for CRN practice settings are endless. In fact, a CRN might work in one of these settings or in multiple settings, depending on the components of the CRN role fulfilled in the position.

Acute Care

One of the most common CRN practice settings is the hospital-based or academic-based clinical research center. Within the acute care setting, the CRN may work on a discrete unit dedicated to the care of the research participant (both inpatient and outpatient), or they may be part of a

research program that provides research support to participants throughout the institutional departments. The department could be one area of focused specialty or multiple specialty areas. The CRN can also work on intensive care units to collaborate with the bedside nurse in performing research-specific activities. In addition, the CRN may work in a research support office setting directing human subjects protections or managing research operations.

Community

Within the community, CRNs practice with private physicians' offices coordinating and implementing research protocols. In these setting, a CRN might be the only research specialist in the practice or may be part of small group of CRNs working within the practice. CRNs are also asked to work with research participants within a variety of community settings. The CRN leads recruitment of participants by directly engaging within the communities. The research assessment might be completed within the community or at the participant's home for the convenience of the participant or for the accurate assessment of the social context of the problem. The CRN can lead these types of visits, balancing the needs of the protocol with the safety of the participant.

Office Practice

CRNs practice in various roles in the office setting. The office setting might be part of a pharmaceutical company where the CRN provides expertise in protocol implementation, regulations, and participant safety, or an office in a government agency where the CRN reviews protocol data as part of an auditing process or developing and providing education to CRNs.

Ultimately, the CRN can engage participants in the research process throughout the health care industry and the community. The CRN understands the importance of the appropriate setting based on the activity being conducted and ensures the safety of the participant at all times.

Special Care Facilities

Lastly, CRNs encounter research participants in special care facilities. Special Care Facilities can include rehabilitation, Alzheimer's (or other cognitive impairment) care, assisted living, palliative care, and nursing home facilities. Special care is needed when working in these environments to ensure the safety of these vulnerable populations and coordinate care with the facility staff.

Roles and Practice of the Clinical Research Nurse

In 2007, a role delineation study of 109 clinical research nurses identified the following distinct roles: nurses at the bedside providing direct care to participants in clinical research trials, nurse

managers and supervisors, nurse researchers, clinical research coordinators, educators, and advanced practice nurses (Mori, Mullen, & Hill, 2007). Clinical research is conducted in a wide variety of settings, making it of utmost importance that those caring for research participants are familiar with the ethical, regulatory, fiscal, and clinical issues surrounding the conduct of clinical research. Because of the emphasis on accurate data collection and adherence to the research protocol in the conduct of clinical research, it is not ideal to assume that staff nurses can carry out clinical research activities in addition to providing clinical care. The knowledge and expertise of the CRN related to the conduct of clinical research, protocol activities, and human subjects protection is imperative to the successful outcome of the clinical research process and is best managed by the nurse educated and working in the specialty of clinical research (Offnehartz, McClary, & Hastings, 2008).

DiGiulio (1996) described the need to expand the role of the CRN, suggesting a broader scope than had previously been described. The roles included educator, ally, direct care giver, coordinator of care and research, administrator of research resources, and participant in the conduct of the study. It is clear that CRNs have fully adopted these roles. As discussed above, more recent work provided a taxonomy for clinical research nursing to include the domains of human subjects protection, care coordination and continuity, contribution to clinical science, clinical practice, and study management (Castro et al., 2011). (See Figure 1). These taxonomies have been adopted as the domains of practice for the specialty of clinical research nursing and are used here to describe the practice elements of the CRN role. Although each domain requires a unique set of skills and knowledge, the domains are not necessarily discrete and, depending on the role of the CRN, may overlap in practice.

Domains of Practice for the Clinical Research Nurse

Human Subjects Protection

Nurses in any setting are patient advocates. This is especially true in the specialty practice of clinical research nursing. The domain of human subjects protection emphasizes this responsibility and the importance of keeping research participants safe in the conduct of clinical research, research interventions, and protocol activities. While there are many entities charged with human subjects protection, in clinical research the CRN is the person directly involved with the research participant, making their role as advocate even more significant.

Informed consent is a key element in clinical research, and the CRN facilitates the initial and ongoing informed consent/assent process. The CRN must be knowledgeable about the research protocol in order to facilitate the consent process, answer questions throughout study participation, support the research participant's goal for participating or terminating participation in a study, ensure ongoing consent, and guard against therapeutic misconception.

To that end, the CRN is knowledgeable in human subjects protection principles, federal and global protections, and guidelines. The CRN facilitates informed participation of diverse populations. The CRN continually assesses risk and coordinates research activities to minimize participant risk. The CRN collaborates with the interdisciplinary team to address ethical concerns and conflicts and manages potential personal ethical and financial conflicts of interest.

Care Coordination and Continuity

This domain focuses on integrating research and clinical activities in order to meet the clinical needs of the research participant across the health care continuum, complete protocol activities, and communicate with referring primary providers when necessary. In creating a plan for the research team and research participant, the CRN provides nursing leadership within the interdisciplinary team. Because CRNs will have in-depth knowledge of protocol requirements and expertise in the care of research participants, they often facilitate the education of the research team related to study requirements. The CRN and the research team ensure that the plan of care for the research participant is safe and allows for effective collection of clinical research data (Castro et al., 2011). They also play a pivotal role in educating the research participant, family, and significant others about the protocol requirements and the impact of activities. In addition, they coordinate study visits and facilitate the research participant's questions and concerns.

Contribution to Science in General and Nursing Science/Practice

As important members of the research team, CRNs in a variety of roles in the research enterprise make important contributions to science in general and specifically to nursing science and practice. Established educational and career paths in nursing allow CRNs to work in a variety of roles that are grounded in the holistic care of persons. Nurses prepared at the baccalaureate level through the research doctorate level function in roles including staff nurse, advanced practice nurse, manager, and nurse researcher/scientist. These CRNs engage in specific actions that are essential to the integrity of the scientific process and must be appropriate to their educational background and professional role.

CRNs at all levels may serve as mentors to new study staff and scientists. Staff nurses may offer expertise in operationalizing research protocols in the environment, or they also mentor new study staff in the safe conduct of clinical research. Nurse scientists may advise scientists in methods commonly used in nursing research or serve as clinical experts in specialty areas that uphold the integrity and quality of the research. CRNs are well positioned to generate practice questions based on the new interventions and innovations they work with in the clinical environment, as they are often the first to use an innovation in the patient care context. CRNs are involved in data management, query, and analysis of research data. As a

result of their specialized focus, CRNs generate critical questions regarding both clinical practice and nursing research.

Clinical Practice

The domains of practice developed for CRNs define clinical practice as using the nursing process to provide direct nursing care and support to participants in clinical research, their families, and significant others. Care requirements and protocol activities are determined by the scope of study participation, the clinical condition of the participant, and the requirements and clinical effects of research procedures and protocol requirements (Castro et al., 2011).

The staff nurse, by contrast, has a different focus on standards of care. The goals and expected outcomes for the two nursing practices are very different. The generalist staff nurse cares for the patient based on treatment goals, while the CRN cares for the research participant with research-specific aims in mind. Because of their expertise and knowledge of the clinical research process, CRNs are capable of balancing the care needs of the research participant with the research protocol. This domain of Clinical Practice may include specimen collection; data collection; administration of research interventions; operationalization of the research protocol on the clinical unit; and education of research participants, families, and significant others related to the research protocol requirements and the participant's current clinical condition and/or disease process (Castro et al., 2011). CRNs providing clinical care monitor research participants and are often the first to report adverse events. Their precise assessments skills and documentation are essential for accurate data analysis, thus ensuring definitive findings of the clinical trial.

Study Management

Study Management is defined as management of clinical and research support activities to ensure participant safety, addresses clinical needs, and ensures protocol integrity and accurate data collection (Castro et al., 2011). Some of the activities associated with this domain include study development, participant recruitment, identification of clinical care implications during study development, and recording and managing data to ensure date integrity. Figure 2 below graphically represents this domain of clinical research nursing.

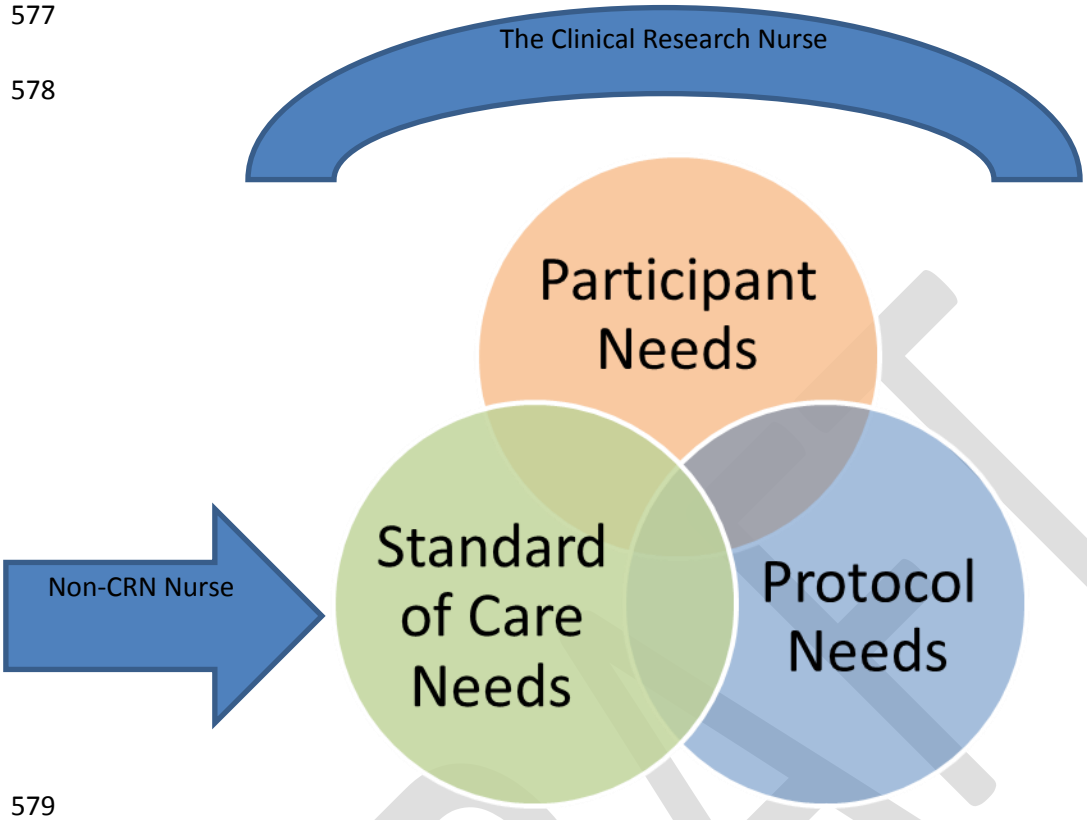
The study management domain comprises the largest set of activities within the CRN domains of practice. The activities associated with this domain are those that most closely represent the specialized knowledge of clinical research. The CRN brings together the specialty knowledge of the research enterprise with that of clinical nursing skills to expertly carry out those tasks associated with study management. The CRN is well situated to support the intersection of the management of the protocol while safeguarding the participant.

The generalist staff nurse and the clinical research nurse have different objectives when approaching a participant in a clinical trial. While the generalist staff nurse without specialized research knowledge provides care with a goal of treatment, the CRN must manage the care of the participant with a focus on the objectives of the research protocol that are not necessarily treatment focused. It is this balance between participant safety and fidelity to the protocol that demonstrates the value of the specially practice.

Implementation of a study protocol alone is a complex process. A clinical protocol that engages health controls or participants with the target disease requires the critical thinking skills of the CRN in order to implement the protocol within the health care framework. CRNs' specialty knowledge allows them to assess the protocol for areas that might affect participant safety and develop processes to protect the participant while still collecting the necessary data in an accurate and timely manner. For example, serious adverse events (SAEs) may occur during the conduct of a clinical trial. The CRN can manage the safety of the participant by adequately addressing the acute medical needs of the participant while collecting and reporting the necessary data mandated research regulations. The CRN's "unique contributions and skills allow him or her to be an integral component to the safety-reporting process" (Catania, 2012, p.18). In addition, CRNs often need to develop methods for data collection that have not been used before. Understanding the nuances of protocol implementation and potential pitfalls is essential to the successful implementation of clinical research.

Adequate recruitment of participants in clinical trials is essential to trial results. Appropriate informed consent process during the recruitment phase is important to protect the participant, ensure the participant's autonomy in decision-making, and increase the chance of retention in the clinical trial. It has been repeatedly demonstrated that the CRN is central to the recruitment and informed consent processes (Isaacman & Reynolds, 1996). CRNs are able to utilize foundational knowledge of their nursing practice integrated with the thorough understanding of the research process, research regulations, and the protocol to safeguard the participant.

Figure 2. Graphic Representation of the Study Management Domain



While the domains of practice outline the work of the CRN, the titles and roles specific to the practice vary. All CRNs, regardless of title, ensure human subjects protection and contribute to the science. The study management, coordination of care, and clinical practice domains are more dependent on the specific title and job description of the CRN in each practice setting. While there is overlap in the roles and responsibilities among position titles, the focus of each title is unique. CRNs are essential to the conduct of clinical research with humans because of their skills, education, and expertise related both to nursing and to clinical research.

Roles of the Clinical Research Nurse

Over the past 30 years, clinical research has expanded in complexity, regulatory oversight, and workload. As a result, the role of the CRN has developed into a specialty practice in contemporary nursing practice (Getz, 2013; Getz, 2009; Mueller, 2001). As the clinical research enterprise has matured, clinical research nursing practice has become more clearly delineated. Nurses comprise a significant component of the clinical research workforce, holding a variety of roles commensurate with baccalaureate through doctorate education. Clinical research is

conducted in a wide variety of settings; therefore, it is of the utmost importance that nurses caring for participants involved in clinical research are familiar with current ethical, regulatory, fiscal, and clinical issues affecting the conduct of clinical research. Due to the nature of the work and the high-stakes outcomes, it is imperative that nurses practicing in clinical research have training specific to research. The knowledge and expertise of the CRN as it relates to participant care, the conduct of clinical research, protocol activities, and human subjects protection are paramount to the success of the clinical research enterprise.

Presently, roles integral to clinical research nursing practice include clinician (direct care provider, study coordinator, and APRN), manager, educator, advocate, and regulatory specialist. Nurses come to each of these roles with educational background varying from baccalaureate to doctoral level preparation; therefore, the level of practice in each of these roles varies from entry-level generalist to advanced practice and senior leadership. Specific titles and nursing activities in these roles vary across organizations and according to the individual's educational preparation. Positions that CRNs hold may involve elements of some or all of the roles identified. Most of the current CRN practice is concentrated in these roles; however, nurses will continue to take on new roles within the CRN practice as the specialty matures.

Clinician

Direct Care Provider: The nurse new to clinical research practice comes to the specialty with a solid skill set based on understanding the nursing process and basic developmental, psychosocial, cultural, and physiological aspects that contribute to human health and wellness. Having achieved mastery of the essential basic nursing interventions, their focus is clinical practice and care coordination related to protocol activities and care of the research participant. They are not directly involved in study management but play a crucial role in ensuring correct implementation of study-related activities requiring specific skills, research education, and expertise.

The experienced research clinician is generally a baccalaureate-prepared CRN who supports study implementation within the context of a care delivery setting. The CRN practices with a clinical research focus, supporting study implementation, balancing the care of the research participant with the requirements of the study protocol, adhering to human subjects protection standards, ensuring participant safety, contributing to quality data collection, and educating participants and families (Hastings et al., 2012). Examples of positions that a direct care provider CRN may hold include bedside nursing in either a dedicated clinical research hospital or clinical unit, or ambulatory nursing on a study team providing care to study volunteers in a variety of settings including the community. Specific role activities within these positions will vary; however, a primary focus of the nurse at this level is to provide direct

nursing care, support, and education to participants in clinical research, their families, and significant others.

Examples of job titles that could be used for this level of practice are Staff Nurse One in a hospital setting, Clinical Research Staff Nurse, Trials Nurse, Outpatient CRN, or Community Research Nurse. The staff nurse practicing as a CRN must be knowledgeable of the regulatory accountability consistent with providing nursing care to a research participant. At this level of practice, this regulatory knowledge and resulting advocacy sets CRN practice apart from generalist nursing practice.

Clinical Research Nurse Study Coordinator: The clinical research nurse coordinator manages the conduct of multiple clinical trials, including the direct care of participants and data collection for clinical trials. This role requires advanced coordination and management skills. Required training can be achieved through research-specific education or may include Master's-level clinical research-focused academic preparation. Job titles that could be used for this level of practice are Clinical Research Coordinator, Study Coordinator, or Project Manager. Nurses in this position are primarily responsible for study coordination and data management, with a central focus on recruitment and enrollment, consistency of study implementation, data management and integrity, and compliance with regulatory requirements and reporting. The CRN with a clinical research coordinator role may or may not participate in direct clinical care of the participant but is directly involved with study management and coordination of care, educating participants, families, and members of the research team and acting as a liaison for sponsors and Institutional Review Board (IRB).

Advanced Practice Registered Nurse (APRN): In clinical research, the role of advanced clinician is often held by an APRN. Advanced practice nurses are well-suited to clinical research specialty practice. Their advanced clinical knowledge along with research acumen are valuable assets, especially as APRN entry-to-practice is now established at the doctoral level. Advanced practice CRNs may participate on a research unit or service providing advanced nursing care for participants of multiple research protocols. They may hold a leadership position on a research team coordinating and directing care of the participants enrolled in a protocol, or they may hold an IRB management position overseeing the regulatory compliance of active clinical research protocols within an organization. APRNs practicing in clinical research nursing specialty practice roles incorporate all aspects of the CRN role: educator, manager, clinician, advocate, and regulator at an advanced level of practice.

<u>Manager</u>

CRN managers leads discrete clinical research units, centers, ambulatory research practices, or research hospitals. They may also manage research programs at the institutional level, as well

as administrative infrastructure management. Typically, these nurses are Master's-prepared, with the knowledge of both health care environments and regulations of the research environment.

Examples of titles associated with this role include Nurse Manager, Program Director, Research Services Nurse Manager, or Participant Interactions Manager. The CRN manager's goal is ensuring availability of appropriate resources throughout the clinical research enterprise with a focus on study implementation and management. In addition, nurses in this role manage physical and human resources with an emphasis on compliance with research regulations.

Educator

CRN educators are often based in institutions that support clinical research. They may hold Master's degrees in education in addition to being nurses. The CRN educator uses expertise in both the education of nurses with that of the research process to develop CRN-specific education, in-services, and orientation materials. Examples of titles for this role include Research Nurse Educator or Nurse Consultant.

Advocate

All CRNs, regardless of the job title, function in an advocate role. There is, however, a group of CRNs who focus their efforts solely on participant advocacy safety. The CRN advocate might come to the role as an ethics nurse, with a doctorally or Master's-prepared in-depth knowledge of the ethical principles in the protections of human subjects. The CRN advocate may serve as a consultant to a study team on matters of informed consent, assess voluntariness of research participants when questions of coercion might arise, or work with scientific and oversight committees such as the IRB in review of protocol safety. Some CRN advocates have a standing role on IRB committees. Examples of titles associated with the CRN Advocate include Research Participant Advocate, IRB Safety Coordinator, or Research Ethics Director.

Regulatory Specialist

The CRN regulatory specialist is a research nurse who monitors and oversees the progress of a clinical trial to ensure that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures, Good Clinical Practice (GCP), and applicable regulatory requirements. They may do this in the setting of the research practice, center, hospital, within industry, or governmental agencies. The CRN regulatory specialist must have advanced knowledge of regulatory science. This training is achieved through various research specific continuing education or Master's education with a focus on regulatory science. Examples of titles for this specialist include Clinical Research Associate, Monitor, IRB Director, and Quality Assurance Manager.

Doctorally-prepared Clinical Research Nurse

Specialist nurses prepared at the doctoral level and practicing as CRNs work in interdisciplinary teams with physicians, laboratory scientists and technologists, pharmacists, institutional review boards, social workers, hospital administrators, and contract officers within institutions to balance the risks and benefits of clinical research studies in order to achieve the optimal outcomes for the participant and the science.

CRNs with doctoral preparation include nurses prepared at the DNP and PhD level. Both types of doctorally-prepared CRNs incorporate most or all the roles integral to clinical research nursing practice in their position: educator, manager, clinician, advocate, and regulatory specialist. Although both hold senior leadership positions in the clinical research enterprise, their primary focuses and contributions differ.

CRNs prepared at the DNP level hold positions focused on using existing knowledge and research to advance nursing practice. They may provide advanced nursing care to research participants or hold senior level administrative positions.

Nurses prepared at the PhD level have a primary focus of contributing new knowledge to the discipline of nursing. Activities the PhD CRN undertakes to achieve this include conducting original research and contributing to theory development at all levels.

Tenets of Clinical Research Nursing

1. **Caring and health are central to the practice of the clinical research nurse**.
The specialty of clinical research nursing integrates caring, health, and clinical research with the aims of human subjects protection and improving healthcare globally. Promoting a healing environment and building positive relationships between the nurse and individual participants and their families are central to the CRN's practice of caring and the guiding principles of research. The CRN extends the values of caring to self, society, and the environment and considers the impact of research on each. More specifically, the nurse scientist promotes health through investigations of ways of caring (Institute of Medicine, 2010). The ultimate reward for CRNs is the awareness that the research they are conducting is likely to have "a positive benefit for patients both now and in the future" (Gibbs & Lowton, 2012, p. 39) .

2. **Clinical research nursing practice is individualized**.
The CRN supports advancement of health equity in research through respect for diversity and a focus on identifying the unique needs of the individual research participant or situation. CRNs individualize practice using knowledge of the core, ethical principles of research involving human subjects respect for person, beneficence, and justice (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978). The research participant is defined as the individual, family, group, community, or population who is the

focus of investigation and to whom the clinical research nurse is providing services, as sanctioned by regulatory bodies.

3. Clinical research nurses use the nursing process to plan and provide individualized care for research participants.

In collaboration with the research participant and inter-professional research team, the CRN applies the nursing process to individualize the health care plan with thoughtful consideration to preserving fidelity to the research protocol. The CRN advocates for the best interest of the research participant and continuously assesses their condition, needs, and outcome responses to appropriately evaluate effectiveness of care, research interventions, and the situation in relation to identified goals and outcomes. CRNs employ critical thinking to synthesize the current body of evidence, knowledge of research regulations, and research experience to inform decisions and individualized care throughout the nursing process.

4. Clinical research nurses coordinate care of research participants by establishing partnerships.

"The CRN coordinates research and clinical activities to meet clinical needs, complete study requirements, and manage linkage with referring and primary care providers" (Castro et al., 2011, p. 78). As a strategic member of the research team, the CRN establishes partnerships with research participants, families, groups, and populations, as well as research colleagues and interprofessional healthcare providers, to meet the needs of those being served. "Successes in clinical research greatly depends on effective communication with members of the research team" (Jones, Croudass, & Lewis, 2010, p. 23). The CRN demonstrates qualities of emotional intelligence in all interactions and selects the most effective communication approach and/or system by which to conduct discussions and convey shared goals. Further, the CRN uses appropriate, effective communication strategies to assess the potential volunteer/research participant's comprehension of the risks and benefits associated with specific research activities, from which to make informed decisions to take part in research or continue participation. The CRN observes for therapeutic misconception and takes appropriate action when it is identified.

5. A strong link exists between the professional work environment and the clinical research nurse's ability to provide quality health care and achieve optimal outcomes.

CRNs endorse the American Nurses Association's position on the nurse's "ethical obligation to maintain and improve health care practice environments conducive to the provision of quality health care" (ANA, 2015, p. 9). CRNs recognize their role in creating, advancing, and sustaining healthy work environments in which to conduct clinical research and the mounting evidence that links healthy work environments to the quality aims of safe, effective, efficient, timely, patient-centered, and equitable care (Institute of Medicine & Committee on Quality of Health Care in America, 2001). The work environment not only affects outcomes in the current work environment, it also influences health care decisions of the future, through the accuracy and

quality of data collected. Additionally, healthy work environments encourage retention of nurses with advanced clinical research nursing experience and expertise (Cohen, Stuenkel, & Nguyen, 2009).

Principles that Guide Clinical Research Practice

Clinical research nursing practice is guided by human subjects protection in the following fundamental principles.

Safety and Self-Determination

Each research participant encounter is carried out with utmost care, compassion, and professionalism to embrace the core values of respect, beneficence, and justice (National Commission for the Protection of HumanSubjects of Biomedical and Behavioral Research (1978).

- Each research participant is recognized as an autonomous being, free to make decisions for themselves and to enter into research voluntarily. CRNs follow ethical guidelines and regulatory requirements that protect those unable to make decision in their own best interest and guard against coercion imposed by others and activities that may harm them.
- Research protocol plans maximize benefits and minimize risk to the individual participant to ensure harm does not come to one person in the pursuit of possible benefits to others.
- Research participants are selected for reasons directly related to the research problem being studied, not because they are easily manipulated, available, or vulnerable. Benefits and burdens in a research study are justly distributed through fair procedures.

Research Informed Consent

The process of informed consent is jointly comprised of three essential elements - provision of complete and accurate information, assessment of comprehension, and safeguards to protect voluntary participation. Employing these elements ensures that participants are given adequate opportunity to choose what will or will not happen to them.

- The participant understands the information and volunteers to participate in clinical research free from coercion.
- The potential participant has sufficient time to consider information provided on all available options in order to make an informed decision to participate or not.
- The informed consent process is ongoing throughout the participant's enrollment in a research study; information is provided as the participant requests it or as the situation

requires it. An opportunity to ask questions and receive a response begins during initial consenting and continues throughout the remainder of participation in the study.

- Information is provided in such a way as to avoid therapeutic misconception. When instances of therapeutic misconception are suspected or identified, information is provided to clarify the participant's understanding of the purpose of the research, and their wish to continue is confirmed.

Fidelity to the Research Protocol

Research studies are conducted as planned, with strict adherence to the design to reduce or eliminate protocol deviations.

- All essential elements of interventions are delivered in a comparable manner, thereby advancing the study's aim(s) (Bellg et al., 2004; Calsyn, 2000; Dumas et al., 2001; Kerns & Prinz, 2002; Nigg, Allegrante, & Ory, 2002).
- Confidence in the study's findings is dependent on strict adherence to the protocol plan and internal validity, thus facilitating the accurate association between the intervention and study outcomes (Calsyn, 2000; Horner, Rew, & Torres, 2006; Kerns & Prinz, 2002).

Regulatory Compliance

All human subjects research is conducted in compliance with federal regulations, state laws, and institutional policies. It is the duty of the CRN to understand and uphold appropriate regulations. Federal regulations governing the protection of human subjects participating in biomedical and behavioral research are codified in the Federal Register in 45 CFR 46, including subparts A, B, C, and D, and 21 CFR 50 and 56 (International Compilation of Human Research Standards, 2015).

Summary

The primary duties of the CRN in the research setting are (1) protection of human subjects; (2) fidelity to the IRB approved research protocols; and (3) strict adherence to research guidelines, regulations, and policies. When these duties are rigorously applied together, they result in safe environments for conducting research and producing reliable, valid data on which to base future health care decisions, treatments, and interventions.

CRNs collaborate with interprofessional research teams to establish processes and employ methods that safeguard against biased selection, involuntary participation, and inappropriate balance of risk and benefits.

Professional Nursing Ethics in Clinical Research Nursing Practice

The *Code of Ethics for Nurses with Interpretive Statements* (ANA 2015) provides a framework for ethical nursing practice in the clinical research setting. While all provisions of the code are applicable to the practice of the CRN, several have increased significance due to the sensitive nature of clinical research, the populations participating, human subjects protection, and the wide ranging practice environments. The following are specific examples of the application of Provisions 1 through 9 that are significant for the CRN.

Provision 1

The nurse practices with compassion and respect for the inherent dignity, worth, and unique attributes of every person.

CRNs encounter potential volunteers and care for research participants with a broad spectrum of conditions, from healthy volunteers to those with severe disease. CRNs establish trusting relationships with participants through respect for human dignity, setting aside any bias or prejudice that may have caused the condition under investigation. A decision to participate in clinical research is made for many reasons. The CRN assesses the participant's understanding of information necessary to make an informed decision to volunteer or continue to participate in clinical research, demonstrating respect for volunteers and supporting their right of self-determination.

Provision 2

The nurse's primary commitment is to the patient, whether an individual, family, group, community, or population.

The CRN continually assesses the care of the research participant and the conditions set forth in the research protocol to meet the needs and requirements of both. Primacy of the participant may be subject to protocol requirements. Using principles of Good Clinical Practice (GCP), the CRN balances advocacy for both the safety of research participants and the efficacy of the research protocol. When conflict between the protocol and best interest of the participant arises, the safety of the participants remains the primary consideration. The CRN is in a unique position to evaluate the participant's understanding of the research in which they are participating and access resources to resolve outstanding questions associated with participation. As new information affecting health, welfare, or willingness to continue participation becomes available, the CRN "may serve as the first line of communication to participants and family members about study progress, evolving concerns, and next steps"

(Hastings et al., 2012, p. 151). The CRN's knowledge of the research protocol's requirements, understanding of the participant needs and wishes, and awareness of available resources enables the CRN to identify a plan of care that is both acceptable to the participant and without protocol conflict. CRNs are often the first to identify and report adverse effects of a new drugs or devices or identify unsafe processes and recommend alternates that support safety and integrity of the data. The CRN advocates for participants by following regulations protecting human subjects that include monitoring for therapeutic misconception and coercion.

CRNs often have duel responsibility to safely care for the participant and maintain fidelity to the research protocol. CRNs may experience conflict arising from requirements of the research protocol, enrollment enticement, expectations of the workplace or sponsoring entity, and their own personal values and professional integrity. It is essential that the CRN continually examine conflicts arising between their own personal and professional values and interest, the research participant's appropriateness for the study, and financial incentives for enrollment and potential for future studies.

The CRN collaborates with other members of the interdisciplinary research team to ensure collection of quality data from which to base future health care decisions, treatments, and standards. The complexity of research requires interprofessional collaboration to maximize safety, minimize risk of those participating, and limit threats to the integrity of the data. Prior to study initiation, the CRN collaborates with members of interprofessional research teams to plan and prepare how the protocol activities will be carried out safely while maintaining integrity of the data. During the active phase of a study, the CRN collaborates with the interprofessional research team when conducting interventions, monitoring and documenting participant conditions, collecting research specimens and data, and providing care to the participant, as appropriate.

Provision 3

The nurse promotes, advocates for, and protects the rights, health, and safety of the patient.

The CRN advocates for an environment that protects human subject's privacy. The patient must provide permission to access personal health information (PHI), which limits access only to the information necessary to maintain the integrity of the clinical trial and conduct the study safely. For example, a waiver of consent from the IRB is required to screen PHI for potential volunteers. The commencement of electronic medical records has presented the research environment with unique privacy challenges. The CRN appropriately manages risk associated with "stigmatizing" studies that include populations at high risk for discrimination if participation is disclosed beyond the research team. Examples include studies examining mental health or social life choices, as well as those enrolling participants who may have a

genetic risk for a specific disease but who have not been diagnosed with the disease. In addition, some clinical research includes tests for specific stigmatizing components not required for treatment that may impact access to health care resources, such as radiographic imaging and laboratory results. The CRN participates in the development and maintenance of policies and practices that protect sensitive information. Collaboration with other members of the research team is essential to ensure that clinical research participants are appropriately protected and that findings are properly documented using methods that both limit exposure and ensure safety. It may be necessary for the CRN to participate in the process to identify stigmatizing information in such a way that it is appropriately available to health care providers without disclosure of identifiable and stigmatizing information. To accomplish this, guided by informed consent, the CRN collaborates with information system professionals and ancillary services to establish and operationalize this process.

It is essential that the CRN is knowledgeable in the area of regulatory oversight. The CRN must be familiar with institutional policies and government regulations that oversee clinical research and govern protection of clinical research participants. Additionally, the CRN values guidelines such as the International Conference on Harmonisation (1997) that provides global standards for the conduct of clinical research and defines Good Clinical Practice (GCP), thus aligning and standardizing conduct of research involving human subjects internationally. The CRN recognizes that these policies, regulations, and standards are in place to protect the rights of human subjects participating in research and "ensure the results obtained from clinical research are reliable and valid" (Hastings et al., 2012, p. 154).

Human subjects protection is one of the main roles of the CRN. This protection includes advocating and educating potential volunteers, participants, and legal representatives in the informed consent process. CRNs are often delegated the responsibility for obtaining informed consent by the principal investigator of the research study. They follow standards and implement mechanisms to conduct reviews that strive to ensure appropriateness of the informed consent. The CRN recognizes that consent is not simply a signature on a document; rather, it is an ongoing process of communication involving the participant, caregivers, and key members of the research team and medical care team. The CRN supports elements of the initial and ongoing informed consent process that includes disclosing relevant information, ensuring comprehension of the information, and supporting voluntary agreement free from coercion.

The CRN acts as a moral agent and advocates for those participating in clinical trials, playing a vital role in keeping paticipants and colleagues safe from risks associated with experimental agents. The CRN participates in the development and implementation of policies and guidelines that provide instruction on handling of experimental agents and instruction on protective measures for CRNs, participants, and family members.

Provision 4

The nurse has authority, accountability, and responsibility for nursing practice; makes decisions; and takes action consistent with the obligation to promote health and to provide optimal care.

CRNs are often employed in settings that dictate considerable autonomy and often work with study teams lead by medical staff and non-clinicians. As a result, interprofessional research teams rely on CRNs for their clinical expertise, knowledge, and skills. The research setting provides CRNs with an opportunity to educate the research team on the nurse's scope of practice and appropriate delegation of duties. Additionally, CRNs interacting with registered nurses in clinical settings frequently find that their role is not well-understood and that other clinicians lack an understanding of the differences between clinical care (aimed at benefiting the current patient) and clinical research (aimed at benefiting future patients and generating generalizable knowledge). CRNs can take this opportunity to educate nurse colleagues on their role in clinical research.

Responsibility and accountability for individual practice is a valid concern for CRNs who may carry out protocol-related activities in a less structured setting lacking the support afforded nurses working in other more traditional care locations. This lack of structure requires the CRN to be self-motivated, accountable, and responsible for both the care and oversight of those participating in clinical research, as well as the responsibility to maintain strict adherence to the clinical research protocol requirements. Clinical research often lacks established standard operating procedures and job descriptions, requiring the CRN to develop competencies in this specialty primarily from peers with clinical research experience and expertise.

Provision 5

The nurse owes the same duties to self as to others, including the responsibility to promote health and safety, preserve wholeness of character and integrity, maintain competence, and continue personal and professional growth.

In some instances, moral distress may occur due to the duality of the CRN role; competing priorities are often at play (Fisher & Kalbaugh, 2012). Demands of the research environment that require the balance of healthcare decisions within the limitations of the research protocol can be challenging. The CRN must seek educational opportunities and identify supportive resources that will inform decisions and preserve moral competence when faced with ethical dilemmas of competing priorities. Expectations of others may exceed the CRN's scope of practice and jeopardize the health and welfare of the CRN, participants, and colleagues. Work settings that isolate CRNs from more formal nurse leadership systems and other nurse colleagues may compromise their ability to advocate for themselves. The structure provided by

a professional association for CRNs provides support from colleagues, offers education, and presents networking opportunities to meet such challenges.

Research protocols often require activities that differ from institutional policies and procedures or what is expected of nurses providing standard-of-care. It is important for the CRN to have specialized training, education, and adequate experience to complete these research requirements competently and safely (Hastings et al., 2012; McCabe & Lawrence, 2007).

Provision 6

The nurse though individual and collective effort, establishes, maintains, and improves the ethical environment of the work setting and conditions of employment that are conducive to safe quality health care.

When engaged in the clinical research process, CRNs have an opportunity to influence the environment in which they practice. In the unique environment of clinical research, fair and respectful treatment of those participating in a clinical trial is a core value. In addition, CRNs recognize the value of the participant's contributions and therefore have an obligation to collect accurate data from which study outcomes will be measured. The CRN fosters an environment that supports elements of respect, beneficence, and justice. CRNs recognizes that those who participate in research must be given the choice of what shall and shall not happen to them, and nurses facilitate this by creating a culture of sharing information, ensuring comprehension, and safeguarding voluntary participation. The CRN fosters the principles of maximizing benefits, minimizing risk, and cultivating an environment that supports fair distribution of benefits and burdens. Solutions for unsafe or inappropriate activities and practices are directed though appropriate institutional channels, such as the IRB.

Provision 7

The nurse, in all roles and setting, advances the profession through research and scholarly inquiry, professional standards development, and the generation of both nursing and health policy.

The practice environment of the CRN exists in a setting of intellectual inquiry and seeks to establish evidence to inform practice. In addition to contributing to science by translating research through active management of research protocols and participating in human testing, CRNs are obligated to advance their own specialized practice by developing new knowledge, establishing evidenced-based practice standards, and disseminating knowledge generated through scholarly investigation (Hastings et al., 2012). CRNs are committed to sharing best practices and educating the next generation of colleagues to impart the knowledge, skills, and

ethical principles essential in human subjects research and to establish safe environment in which to investigate new technologies and treatments. Additionally, CRNs review and contribute to current trends in clinical research policy.

Provision 8

The nurse collaborates with other health professionals and the public to protect human rights, promote diplomacy, and reduce health disparities.

Through collaboration with interprofessional research teams, the CRN is in a unique position to move scientific findings from the laboratory to the bedside. Using protection of the public and ethical standards of research as guiding principles, CRNs advocate for quality of research. Through management of clinical research participants and research protocols, the CRN is positioned to contribute to the development of future treatments, thereby advancing the health, welfare, and safety of individuals and communities locally, regionally, nationally, and globally. In addition to fostering fundamental principles for conducting research, CRNs are committed to educating the public on their rights and responsibilities when participating in clinical research.

Provision 9

The profession of nursing, collectively through its professional organizations, must articulate nursing values, maintain the integrity of the profession, and integrate principles of social justice into nursing health policy.

The values of clinical research nursing are advanced broadly and communicated widely through the professional association, IACRN, and its membership. This professional association serves as a conduit to maintain and further the integrity of the specialty practice. It works to align the guiding principles of research with those of social justice and integrate them into nursing policy. The association promotes health, safety, and research integrity by active engagement in educational offerings nationally and globally, including developing research regions.

CRNs serve as experts to guide decisions involving clinical research both in the US and internationally. Guided by the *Code of Ethics for Nurses with Interpretive Statements* and other published standards for research, CRNs influence leaders on research topics through affiliations, committee memberships, publications, expert consultation, and national and international training/education sessions. CRNs influence health policy, model professional commitment to leadership, and share nursing research expertise to advance clinical and translational research through professional collaborations, educational offerings, publications, and committee memberships.

Educational Preparation for Clinical Research Nurses

Baccalaureate education is preferred for entry to clinical research nursing practice. Masters- and doctoral-level nurses can also enter clinical research roles. The current demands of undergraduate nursing curriculum affect the amount of research education included in pre-licensure curriculum. While exposure to evidence-based practice concepts does orient entry-level nurses to the research process, specific nursing roles and elements of clinical research nursing practice are not typically present.

The role of clinical research nursing is not well-articulated in undergraduate nursing curriculum. Learning and practicing the principles central to the care of the research participant are appropriate objectives for baccalaureate-level education. Newly licensed baccalaureate nurses are often unaware of this career pathway or that hundreds of nurses are practicing in CRN roles in a wide variety of settings. The CRN develops competency in this specialty primarily from peers with clinical research experience and expertise (Carter, Jones, & Jester, 2007; Hastings et al., 2012). It is most often during work experience that a newly graduated nurse is first exposed to aspects of clinical research practice. Complete and accurate documentation and assisting with data collection for an investigator or nurse colleague are likely opportunities for first exposure to CRN practice. After gaining clinical experiences, usually in an acute care setting, nurses are often recruited to clinical research specialty positions where they can use their clinical and critical thinking skills in the role of the CRN.

Master's-level students are not exposed to coursework that highlights this role, either. For example, many CRNs prepared at the graduate level are nurse practitioners (NPs), yet few are introduced to the role of the APN in clinical research. Developing a specialty practice with a clinical research focus at this level is a very rewarding choice for many APNs. Few aster's of nursing (MSN) programs offer clinical nurse specialist or clinical nurse leader options in lieu of nurse practitioner options; therefore, many CRNs seeking graduate education in the specialty field of clinical research nursing may seek education in clinical research from the available distance-based academic programs or the limited number of MSN program offerings in clinical research management.

CRNs prepared at the doctoral level (DNP/PhD) hold various roles in clinical research nursing leadership, including administrative positions and research team leadership positions. Although specialty tracks with a clinical research nursing specific focus do not exist for this level of preparation, the foundational knowledge of doctoral education is likely consistent with that necessary for clinical research nursing. As with the baccalaureate and master's levels, the nurse prepared at this level will need to seek out additional education and training to be proficient in the CRN role appropriate to the doctoral level.

The American Nurses Association (ANA) *Guide to the Code of Ethics for Nurses: Interpretation and Application* (2015) highlights the protection of patients participating in research in interpretive statement 3.3. Ethical competence for all nurses is commonly seen as a responsibility of the basic educational preparation of the nurse as well as a personal developmental moral compass (Poikkeus, Numminen, Suhonen, & Leino-Kilpi, 2014). Theory, epistemology, and the best evidence available from basic nursing education foundationally support clinical research nursing practice. In addition, it is critical that CRNs are educated in the research process, good clinical practice guidelines, and associated scientific knowledge. Such education in good clinical research practice protects the rights, safety, and wellbeing of study participants and helps to ensure that data gathered in the pursuit of research are credible and accurate. Through this process, nurses have been integral interdisciplinary partners in the creation of evidence-based practice, especially in the development of drugs, devices, biologics, and combination products that are ultimately marketed to global populations.

Continuing Professional Development for Clinical Research Nurses

Clinical research nursing curriculum content and associated clinical practicum experiences are rarely incorporated in formal academic programs at the undergraduate nursing level, and only a limited number of institutions offer a Master's research program in nursing. Continuing education focused on clinical research nursing is limited, and choices for continuing education and professional development in clinical research nursing are often based on the role that an individual CRN holds or the population in which they work. The goal of professional development is to pursue additional knowledge that will lead to greater ability to perform in the workplace and grow as a professional. Ongoing professional development is necessary to maintain competency and advance knowledge in the growing field of clinical research. The CRN has unique educational requirements that may include knowledge and training specific to research activities or outside the scope of practice for RNs in more traditional settings.

Nurses seeking professional development with an emphasis in clinical research may find educational opportunities through professional organizations, mentoring, on-the-job training, workshops, conferences, training sessions, online learning, regulatory compliance training, and continuing education programs offered by organizations such as the International Association of Research Nurses (IACRN).

Depending on the clinical research practice, CRNs may elect to expand their skills and knowledge in a clinical specialty program based on population of interest or other nontraditional dimensions of the CRN practice such as regulatory compliance, finance, site coordination and study management, and ethics. CRNs and leaders in clinical research are

encouraged to pursue further education and advance their degree at the baccalaureate through graduate levels.

The Institute of Medicine (2010) states, “Nurses should practice to the full extent of their education and training”(p.1). In order to do this safely and effectively, the CRN must take advantage of, and be given opportunities to, further her professional development. The experience, skill, and decision-making abilities of the CRN play a role in participant safety, quality of research data, regulatory compliance, and human subjects protection. Creating a competency framework for the specialty of clinical research nursing based on the domains of practice for the CRN, research specific scope and standards, and core curriculum will provide guidance for professional development.

Specialty Practice Certification for Clinical Research Nurses

As the clinical research enterprise continues to grow, more reliance on the skills of the CRN has emerged. Recognizing their importance in the clinical research process, CRNs began to organize internationally in 2009. The International Association of Clinical Research Nurses (IACRN) was created to support their global contributions. Because the role goes beyond providing direct patient care, elements of the role were identified to define the specialty practice. “Development of a specialty identity that can lead to certification begins with clarification of the domain of practice for the specialty” (Hastings et al., 2012, p. 653).

Importance of Certification

The Pew Health Professions Commission, the Institute of Medicine , the American Board of Nursing Specialties, the American Nurses Credentialing Center, and other professional nursing groups have called for specialty certification as a “means of enriching nursing care, assessing continued competency, after licensure, and improving the quality of patient care” (Boyle, Cramer, Potter, Gatua, & Stobinski, 2014, p. 511).

Nursing requires a license, based on demonstrating knowledge of minimum requirements for an individual to practice. Specialty certification signifies achievement of the specialized knowledge and skills needed for a particular practice area. The nurse seeking to advance knowledge, education, and abilities obtains specialty certification that influences accountability and responsibility, demonstrates mastery of skills, and distinguishes themselves through commitment to lifelong learning and professional growth (Altman, 2011). Specialty certification for the registered nurse working in clinical research will improve participant safety, fidelity to the research protocol, and data collection by validating that practice is consistent with standards identified by a nursing specialty (Boyle et al., 2014).

Certification programs often require proof of ongoing continuing education, which is available through a variety of platforms. There are online learning opportunities, conferences, webinars, and self-study through journals, professional articles, and other educational materials. Certification demonstrates commitment to the profession and professional development.

Need for Certification

Certification for clinical research professionals is available through the Association of Clinical Research Professionals (ACRP) and the Society of Clinical Research Associates (SOCRA). While these organizations may provide a framework for clinical research, they are not specific to nursing and do not address the unique contributions of the CRN in clinical research. Some common certifications CRNs may obtain include oncology, medical/surgical, gerontological, or administrative certifications, but these are not specific to clinical research.

While the presence or absence of certification does not define a practice specialty, it does set expectations based on core competencies. By developing scope and standards, core competencies based on practice domains, and specialty certification, the CRN will have a process in place to demonstrate and validate expertise. In addition, this structure will outline standards for the profession and result in CRNs who foster safe participant care and fidelity to the research protocol.

Trends and Issues in Clinical Research Nursing

Workplace, Participant, and Public Safety

In addition to the common physical work environment risks, CRNs are often exposed to investigational products for which there is limited experience and unknown risk of exposure. Investigational products must be evaluated for risk to the nurse, participant, family members, caregivers, and the public, as well as for compliance with standard workplace safety regulations and institutional policies. CRNs collaborate with healthcare colleagues to evaluate and limit known, potential, or unknown risk and develop safe handling procedures. The CRN's unique assessment skill; knowledge of the research setting, investigational product, and availability of resources; and understanding of the population being enrolled in the research study prepares them to identify possible threats and develop safe handling procedures and educational material to protect individuals who may come in contact with the investigational product or device. CRNs often provide education to protect colleagues, participants, and families by evaluating the participant's comprehension of risk, ability to comply with safe handling procedures and, when the opportunity exists, providing education and training on precautions and protective procedures.

Electronic Health Record

Widespread adoption of electronic health records (EHRs) has transformed the process by which health information is managed and shared. EHRs are currently standard in most healthcare settings with the exception of clinical research. In most cases, clinical research documentation has remained separate from the standard-of-care EHR, although integration of the two may have tremendous potential to support both. Incorporation of clinical research documentation in the EHR will lead to a more complete participant medical history that supports both research and medical records regulations (Broach, 2015). This also results in a safer environment in which to care for research participants. Electronic health data promises to not only contribute to provision of healthcare, but also transform biomedical research; however, without an EHR platform that can accommodates research documentation, CRNs are challenged to integrate the two in one electronic location (Coorevits et al., 2013). Additionally, HIPAA regulations may present information sharing challenges when study teams experience limited access to the comprehensive EHR. In many instances, a second document – outside the EHR – is required to provide a comprehensive picture of the participant that includes both research and standard-of-care activities. EHR platforms that allow for both activities not only ease access to research data but also make information useful for quality improvement analysis and further support safety in the research environment. Immediate access to the EHR improves interdisciplinary communication across the healthcare spectrum. Thus, documentation by the CRN contributes to the participant's health and well-being.

Accuracy of data collection and documentation is of paramount importance when conducting clinical trials. The CRN plays a fundamental role in the management and documentation of data collection related to clinical trials. Documentation for clinical research may differ from documentation required for standard of care. Research data collection and documentation may include clinical observations, clinical measurements, and specimen collection and preparation, not required for standard of care (Hastings et al., 2012). Documentation that is acceptable in the clinical setting often requires additional details when the patient, now a study participant, is enrolled in a clinical trial. The accuracy and quality of the data collected during a clinical trial impacts the reliability of the findings and may impact human subjects safety, the speed at which study results are disseminated, and how health care treatment decision are made in the future. Thus, documentation by the CRN contributes not only to the individual participant’s health and well-being but also to the degree data can be generalized to the larger population.

The CRN differentiates between information reported in the EHR (that is collected strictly for research purposes and provides no diagnostic purpose) from information related to standard-of-care activities. The CRN has knowledge regarding how to comprehensively

document the care provided for research purposes, while being sensitive to the confidential nature of the research information. The CRN recognizes stigmatizing information related to a clinical trial that may be excluded or de-identified without jeopardizing safety or care.

Privacy Issues

Biomedical research is a rapidly growing area of interest in clinical research. Due to the sensitive nature of these research specimens, confidentiality is critical. Many different types of research rely on the use of human specimens. The growth of biomedical research into the origin of disease at the cellular level and the development of bio banks raise ethical challenges, more so than other health information because these specimens may actually predict disease for the participant and for family members (Dye, Youngs, McNamara, Goldblatt, & O'Leary, 2010). When a scientist wishes to collect research specimens from participants in a clinical trial, a detailed plan that describes how the samples will be de identified and how the privacy of the participant will be maintained must be outlined and followed. This plan must be approved by the IRB, and the information must be presented to the participant during the informed consent process. The CRN is likely to encounter complex ethical questions and must be able to identify these ethical situations related to biomedical specimen collection in order to properly inform participants and families of the possible risks related to this type of specimen collection. Additionally, the CRN may be involved in the collection and identification process of these specimens. Often times these biomedical research specimens are collected not for diagnostic purposes, but with the intention to use at a later date for purposes not yet determined. The specimens collected as part of a clinical trial will not likely benefit the person donating them, but hopefully the knowledge gained from studying these specimens may benefit populations in the future.

Increasing Minority Involvement in Clinical Research

Increasing, minority involvement in clinical trials has been a topic of great interest for over 30 year (Fisher & Kalbaugh, 2011). There has been much speculation and literature exploring the reasons for lack of participation in clinical trials by minorities and ways to impact this. African Americans are historically underrepresented in clinical trials (Fisher & Kalbaugh, 2011). The Tuskegee experiments enrolled uninformed African American males in high risk research and were said to have created mistrust in the intention of researchers, especially within the African American community. Other minority groups such as Hispanics and Asian Americans, although not directly impacted by The Tuskegee experiments, have similar mistrust of the research community. This mistrust continues to be cited in the literature today as a barrier to clinical trial participation in minority populations.

Some literature contradicts this notion of mistrust as a barrier to participation. Wendler and colleagues (2006) suggest that, although the mistrust exists, minority populations are willing to participate in clinical trials – they are simply not asked.

Minority involvement in clinical trials is essential to be able to generalize research questions, especially in pharmaceutical trials. It is now widely understood the pharmaceuticals do not work equally in all races, genders, and age groups. Ensuring a broader safety profile in approved drugs lies heavily in inclusion of minority populations, including women and children.

Two major legislative mandates were issued in the 1900s in an attempt to address issues associated with vulnerable and minority populations involvement in clinical trials. The Belmont Report addresses the human subjects protection problems that experiments such as the Tuskegee experiments brought to the forefront. In 1994, the NIH released a new policy mandating the inclusion of minorities and women in clinical research. This policy was revised in 2001. The inclusion policy states: "The objective should be to actively recruit and retain the most diverse study population consistent with the purposes of the research project" (NIH, 2001). These policies have left research study teams with the challenge of gaining trust from minority groups while ensuring their inclusion.

Recent investigations of minority representation have shown that minorities such as African Americans are overrepresented in in Phase 1 studies, which recruit health volunteers, yet remain underrepresented in Phase 2 and 3 studies (Fisher & Kalbaugh, 2011). Interestingly, Phase 1 studies often pose the greatest risk. Until recently, the discussion of minority population involvement by level of risk has had little discussion. This notion brings forth many ethical questions about minority groups taking on greater risk in drugs developed for the general population, in which this group remains a minority.

The recent trend in addressing increased involvement of minorities in clinical research has been a shared approach with the public. Research teams do not just to go into communities and recruit participants in a culturally sensitive way, but rather include the communities of interest in the research questions. The UK has called this initiation Patient and Public Involvement (PPI). PPI is a national effort by the National Institute for Health Research (NIHR; 2015). This effort involves the public in all aspects of clinical research: research questions of interest in the targeted communities, protocol development, review of funding decisions, and education of researchers. In the US, there is a similar movement called community engagement or involvement. The assumption in this model is that, in order for there to be sufficient research volunteers with adequate representation of minorities, the research community must engage communities in all aspects of the research process, including the dissemination of research results (Sung et al., 2003).

For several reasons, CRNs are at the forefront of the effort to increase minority involvement in clinical research. CRNs are able to best address the need to increase minority involvement in clinical research because they utilize their nursing skills such as knowledge of cultural sensitivity care, nursing assessment, and care implementation paired with their specialized knowledge of the research process to advance community engagement in clinical trials. Nurses have been rated by the public as one of the most trusted professional for 12 years in a row, according the Gallup's annual survey (Robert Wood Johnson Foundation, 2014). CRNs can use this confidence to break down barriers of mistrust in clinical research that still exist today. Lastly, because nurses have a long history of community health nursing, CRNs can expertly bring the research to the communities. Adding this experience to their expertise in the research process allows the CRN to successfully implement research projects in community settings. CRNs are the perfect liaisons between the community and the investigators and can help ensure safe, ethical, and just enrollment of clinical trials participants.

Establishing the Evidence for Practice

The CRN's domain of professional practice is positioned at the leading edge of clinical research investigation. CRN activities help to identify the efficacy, maximum tolerated dose, side effect profile, contraindications, pharmacokinetics, and pharmacodynamics of investigational agents, which would otherwise be largely unknown. The astute monitoring, reporting, documentation, and planning by CRNs are essential to the quality and validity of evidence used when determining best practice. The CRN's seminal contributions provide the foundation for evidence-based practice, thereby supporting maximum safety and efficacious outcomes.

Summary of the Scope of Clinical Research Nursing

There is an extensive history surrounding research conducted on human subjects. The role of the registered nurse in clinical research is dynamic. These changes require that CRNs continually update their knowledge and competencies to adapt to this new information. CRNs hold leadership roles in the implementation and management of clinical trials. As education specialists implementing research-specific education and training, CRNs are working together to identify and develop standards for research related activities.

Clinical Research Nursing: Scope and Standards of Practice delineates the professional responsibilities of all professional CRNs engaged in clinical research practice, regardless of the setting. It can serve as a basis for:

- Quality improvement systems;
- Development and evaluation of clinical research nursing delivery systems and organization structures;

- Certification activities;
- Position descriptions and performance appraisals;
- Agency policies, procedures, and protocols (standards); and
- Educational offerings

Healthcare consumers participating in clinical trials require a nurse who understands not only standard of care activities related to their care but also the requirements of the research protocol in which they are enrolled. The CRN must recognize the standard of care activities and protocol activities. They must recognize when differences occur and how to balance care of the participant and fidelity to the research protocol. Accurate data collection is of paramount importance. Monitoring, assessing, and identifying adverse events are critical to the CRN's role.

Caring for participants enrolled in clinical trials allows the CRN to use knowledge and skills in a variety of settings: inpatient and outpatient; standalone clinics; and in community settings with pediatric, adult, and geriatric participants.

The knowledge base required to provide quality care is not achieved through basic or advanced nursing education. The CRN must be a self-motivated learner with the ability to glean information from multiple sources and integrate that information into clinical practice while maintaining fidelity to the research protocol.

The growth of clinical research contributes to the rapidly expanding knowledge base in clinical research nursing. This growth offers an exciting and challenging practice venue for nurses who are self-starters, who want to make a significant impact to nursing practice, and who are dedicated to providing information and education to other healthcare consumers. The CRN must be able to manage the complex research protocol requirements and treatments, in addition to managing the participants' comorbidities. CRNs have the ability and desire to pioneer a relatively new and continually evolving specialty in nursing.

Standards of Clinical Research Nursing Practice

Significance of the Standards

The standards of clinical research nursing practice are authoritative statements of the duties that all clinical research registered nurses, regardless of role, population, or specialty are expected to perform competently. The standards published herein may be utilized as evidence of the standard of care, with the understanding that application of the standards is context-dependent. The standards are subject to change with the dynamics of the clinical research nursing specialty, as new patterns of professional practice are developed and accepted by the nursing profession and the public. In addition, specific conditions and clinical circumstances may also affect the application of the standards at a given time (e.g., during a natural disaster). The standards are subject to formal, periodic review and revision.

The competencies that accompany each standard may be evidence of compliance with the corresponding standard. The list of competencies is not exhaustive. Whether a particular standard or competency applies depends upon the circumstances. The competencies are presented for the clinical research registered nurse level and are applicable for all nurses. Standards may include additional competencies delineated for the graduate-level prepared registered nurse, a category that also includes advanced practice registered nurses. In some instances, additional discrete competencies applicable only to advanced practice registered nurses may be included.

Adapted from ANA, 2015, p. 51

Standards of Practice for Clinical Research Nursing

Standard 1. Assessment

The clinical research registered nurse collects comprehensive data pertinent to the research protocol requirements and the research participant's health and/or situation.

Competencies

The clinical research registered nurse:

- Collects pertinent data, including but not limited to demographics, social determinants of health,

- Collects comprehensive data including but not limited to physical, functional, psychosocial, emotional, cognitive, sexual, cultural, age-related, environmental, spiritual/transpersonal, and economic assessments, in a systematic and ongoing process while honoring the uniqueness of the research participant and the research protocol requirements.

- Recognizes the importance of the assessment parameters identified by WHO, Healthy People 2020, or other organizations that influence nursing practice.

- Integrates knowledge from global and environmental factors into the assessment process.

- Elicits the research participant's values, preferences, expressed needs and knowledge of the healthcare situation, research protocol requirements, and risks versus benefits.

- Recognizes the impact of one's own personal attitudes, values, and beliefs on the assessment process.

- Involves the research participant, family, and other healthcare providers as appropriate in holistic data collection, including research data.

- Identifies barriers (e.g., psychosocial, literacy, financial, cultural) to effective communication and makes appropriate adaptations.

- Assesses family dynamics and impact on the research participant's health and wellness.

- Engages the research participant and other interprofessional team members in holistic, culturally-sensitive data collection.

- Prioritizes data collection based on the research participant's immediate condition or situation while maintaining protocol integrity.

- Uses appropriate evidence-based assessment techniques, instruments, and tools not restricted by the research protocol.

- Applies ethical, legal, and privacy guidelines and policies to the collection, maintenance, use, and dissemination of data and information.

- Recognizes the research participant as the authority on her or his own health by honoring their care preferences, including their right to participate or withdraw from the research protocol.

- Documents relevant data in a retrievable format, ensuring IRB requirements for research data.

Additional competencies for the graduate-level prepared clinical research nurse, including the APRN

The graduate-level prepared clinical research nurse or the APRN:

- Initiates and interprets diagnostic tests and procedures relevant to the research participant's current status and study participation.

- Uses advanced assessment skills, knowledge, and tools to complement the assessment process.

- Assesses the effect of interactions among individuals, family, community, and social systems on health and illness.

Standard 2. Diagnosis

The clinical research registered nurse analyzes assessment data to determine actual or potential diagnoses, problems, and issues.

Competencies

The clinical research registered nurse:

- Identifies actual or potential risks to the research participant's health and safety or barriers to health, including those outlined in the research informed consent, which may include but are not limited to interpersonal, systematic, or environmental circumstances.
- Uses assessment data, standardized classification systems, technology, and clinical decision support tools to articulate actual and potential diagnoses, problems, and issues.
- Validates diagnoses, issues, and understanding of research participation with the participant, family, and other healthcare providers when possible and appropriate.
- Prioritizes diagnoses, problems, and issues based on mutually established goals to meet the needs of the research participant and the research protocol.
- Documents diagnoses or issues in a manner that facilitates the determination of the expected outcome and research plan.

Additional competencies for the graduate-level prepared clinical research nurse, including the APRN

The graduate-level prepared clinical research nurse or the APRN:

- Uses information and communication technologies to analyze diagnostic practice patterns of nurses and other members of the interprofessional healthcare team, considering the relevance to clinical research.
- Utilizes complex data and information obtained during interview, examination, and diagnostic processes in identifying diagnoses and determining appropriateness for study participation.
- Employs aggregate-level data to articulate diagnoses, problems, and issues of research participants, research protocols, and/or organizational systems.
- Formulates a differential diagnosis based on the assessment, history, physical examination, and diagnostic test results.

Standard 3. Outcomes Identification

The clinical research regiatered nurse identifies expected outcomes for a plan individualized to the research participant or situation within the parameters of the research protocol.

Competencies

The clinical research registered nurse:

- Engages the research participant, interprofessional team, and others in partnership to identify expected outcomes, when appropriate.
- Formulates culturally sensitive expected outcomes derived from assessments and diagnoses.
- Uses clinical expertise, current evidence-bases practice, and knowledge of the research protocol objectives to identify health risks, benefits, costs, and/or expected trajectory of the condition.
- Collaborates with the research participant to define expected outcomes that integrate their culture, values, and ethical considerations.
- Generates a time frame for the attainment of expected outcomes.
- Develops expected outcomes that facilitate coordination of care.
- Modifies expected outcomes according to changes in the status of the research participant, evaluation of the situation, and management of the research protocol.
- Documents expected outcomes as measurable goals.
- Evaluates the actual outcomes in relation to expected outcomes, research aims, safety, and quality standards.

Additional competencies for the graduate-level prepared clinical research nurse, including the APRN

The graduate-level prepared clinical research nurse or the APRN:

- Defines expected outcomes and research aims that incorporate cost and clinical effectiveness; and are aligned with the outcomes identified by members of the interprofessional team and the research protocol.

- Differentiates outcomes that require care process interventions from those that require system-level interventions.

- Integrates scientific evidence and best practices to achieve expected outcomes within the guidelines of the research protocol.

- Advocates for outcomes that reflect the research participant's culture, values, and ethical concerns.

Standard 4. Planning

The clinical research registered nurse develops a plan that prescribes strategies and alternatives within parameters of the research protocol to attain expected measureable outcomes.

Competencies

The clinical research registered nurse:

- Develops an individualized, holistic, evidence-based plan in partnership with the research participant and interdisciplinary team.
- Establishes both the healthcare and the research plan priorities with the research participant, interprofessional team, and others as appropriate.
- Advocates for responsible and appropriate use of interventions to minimize unwarranted or unwanted treatment and/or research participant suffering.
- Prioritizes elements of the health care approach and research plan based on the assessment of the research participant's level of risk and safety needs.
- Includes evidence-based strategies in the plan to address each of the identified diagnoses, problems, and research protocol objectives or issues. Within the parameters of the research protocol, these strategies may include but are not limited to:
  - Promotion and restoration of health;
  - Prevention of illness, injury, and disease;
  - Facilitation of healing;
  - Alleviation of suffering; and
  - Supportive care
- Incorporates an implementation pathway that describes steps and milestones.
- Identifies cost and economic implications of the health care and research plans.
- Develops a plan that reflects compliance with current statutes, rules and regulations, and standards.
- Modifies the health care plan according to the ongoing assessment of the research participant's response and other outcome indicators, including participant safety, protocol integrity, and research participation termination if necessary.
- Documents the plan in a manner that uses standardized language or recognized terminology.

Additional competencies for the graduate-level prepared clinical research nurse, including the APRN

The graduate-level prepared clinical research nurse or the APRN:

- Designs strategies and tactics to meet the multifaceted and complex needs of research participants.

- Leads the design and development of inter-professional processes to address the identified diagnosis, issue, and research protocol objectives.

- Actively participates in the development and continuous improvement of systems that support the planning process.

- Designs innovative nursing practices.

- Integrates assessment strategies, diagnostic strategies, and therapeutic interventions that reflect current evidence consistent with the research protocol objectives, including data, research, literature, and expert clinical knowledge.

Standard 5. Implementation

The clinical research registered nurse implements the identified healthcare and research plans.

Competencies

The clinical research registered nurse:

- Partners with the research participant, family, significant others, and caregivers as appropriate to implement the health care and research plans in a safe, effective, efficient, timely, patient-centered, and equitable manner (IOM, 2010).
- Integrates interprofessional team partners in implementation of the health care and research plans through collaboration and communication across the continuum of care.
- Demonstrates caring behaviors to develop therapeutic relationships.
- Provides culturally congruent, holistic care that focuses on the research participant and advocates for the needs of diverse populations across the lifespan within the parameters of the research protocol.
- Uses evidence-based interventions and strategies to achieve the mutually identified goals and outcomes specific to the problem, needs, and research protocol objectives.
- Integrates critical thinking and technology solutions to implement the nursing process and research protocol to collect, measure, record, retrieve, trend, and analyze data and information to enhance nursing practice and research participant outcomes.
- Delegates according to the health, safety, and welfare of the research participant and considering the right circumstance, person, task, direction/communication, supervision, evaluation, as well as the state nurse practice act regulations, institution, regulatory entities, and research protocols while maintaining accountability for the care.
- Documents implementation and any modifications, including changes or omissions, of the identified plan.

Additional competencies for the graduate-level prepared clinical research nurse, including the APRN

The graduate-level prepared clinical research nurse or the APRN:

- Uses systems, organizations, and community resources to lead effective change and implement the health care and research plans.

- Applies quality principles while articulating methods, tools, performance measure, and standards as they relate to implementation of the health care and research plans.

- Translates evidence into practice.

- Leads interprofessional teams to communicate, collaborate, and consult effectively.

- Demonstrates leadership skills that emphasize ethical and critical decision-making, effective working relationships, and a systems perspective.

- Serves as a consultant to provide additional insight and potential solutions.

- Uses theory-driven approaches to affect organizational or system change.

Additional competencies for the advanced practice clinical research registered nurse, within the research protocol parameters,

- Uses prescriptive authority, procedures, referrals, treatments, and therapies in accordance with state and federal laws and regulations.

- Prescribes traditional and integrative evidence-based treatments, therapies, and procedures that are compatible with the research participant's cultural preferences and norms.

- Prescribes evidence-based pharmacological agents and treatments according to clinical indicators and results of diagnostic and laboratory tests.

- Provides clinical consultation for research participant and professionals related to complex clinical cases to improve care and research participant outcomes.

Standard 5A. Coordination of Care

The clinical research registered nurse coordinates care delivery.

Competencies

The clinical research registered nurse:

- Organizes the components of the clinical research protocol and, when applicable, a healthcare plan.
- Collaborates with the research participant to help manage health care and protocol activities based on mutually agreed upon outcomes.
- Manages a research participant's care and protocol activities in order to reach mutually agreed-upon outcomes.
- Engages research participants in self-care to achieve preferred goals for quality of life.
- Assists the research participant in identifying options for care.
- Communicates with the research participant, interprofessional team, and community-based resources to affect safe transitions in continuity of care.
- Advocates for the delivery of dignified and holistic care by the interprofessional team.
- Documents the coordination of care, including research activities.

Additional competencies for the graduate-level prepared clinical research nurse, including the APRN

The graduate-level prepared clinical research nurse or the APRN:

- Provides leadership in the coordination of interprofessional health care for integrated delivery of services to achieve safe, effective, efficient, timely, patient-centered, and equitable care (IOM, 2010).
- Manages identified consumer panels or populations.
- Serves as a research liaison to the research participant, family, and community-based physician regarding healthcare issues identified during participation in clinical research when not restricted by the research protocol.

- Synthesizes data and information to prescribe necessary system and community support measures, including modifications of surroundings using knowledge of the research protocol parameters.

Standard 5B. Health Teaching and Health Promotion

The clinical research registered nurse employs strategies to promote health and a safe environment.

Competencies

The clinical research registered nurse:

- Provides opportunities for the research participant to identify needed healthcare promotion, disease prevention, and self-management topics.
- Uses health promotion and health teaching methods appropriate to the situation and the research participant's values, beliefs, health practices, developmental level, learning needs, readiness and ability to learn, language preferences, spirituality, culture, and socioeconomic status.
- Uses feedback and evaluations from the research participant to determine the effectiveness of the employed strategies.
- Uses technologies to communicate health promotion and disease prevention information to the research participant.
- Provides research participants with information about intended effects and potential adverse effects of the health care and research plans of care.
- Engages consumer alliance and advocacy groups in health teaching and health promotion activities for research participants.
- Provides anticipatory guidance to research participants to promote health and prevent or reduce the risk of negative health outcomes.

Additional competencies for the graduate-level prepared clinical research nurse, including the APRN

The graduate-level prepared clinical research nurse or the APRN:

- Synthesizes empirical evidence on risk behaviors, gender roles, learning theories, behavioral change theories, motivation theories, translational theories for evidence-based practice, epidemiology, and other related theories and frameworks when designing health education information and programs.
- Evaluates health information resources for applicability, accuracy, readability, and comprehensibility to help the research participant access quality health information.

Standard 6. Evaluation

The clinical research registered nurse evaluates progress toward attainment of goals and outcomes.

Competencies

The clinical research registered nurse:

- Conducts a holistic, systematic, ongoing, and criterion-based evaluation of the goals and outcomes in relation to the structure, processes, and timeline prescribed by the health care and research plans.
- Collaborates with the research participant and others involved in the care or research situation in the evaluation process.
- Determines, in partnership with the research participant and other stakeholders, the patient-centeredness, effectiveness, efficiency, safety, timeliness, and equitability (IOM, 2010) of the strategies in relation to the response of the health care research plans, and attainment of outcomes. Other defined criteria (e.g. Quality and Safety Education of Nurses) may be used as well.
- Uses ongoing assessment data to revise the diagnosis, outcomes, healthcare plan, and implementation strategies within research protocol parameters.
- Shares evaluation data and conclusions with the research participant and other stakeholders in accordance with the research plan and federal and state regulations.
- Evaluates adherence to IRB-approved protocol.
- Documents the results of the evaluation.

Additional competencies for the graduate-level prepared clinical research nurse, including the APRN

The graduate-level prepared clinical research nurse or the APRN:

- Synthesizes evaluation data from the research participant, community, population, and /or institution to determine the effectiveness of the health care and research plans.
- Engages in a systematic evaluation process to revise the healthcare plan to enhance its effectiveness within parameters of the research protocol.
- Uses results of the evaluation to make or recommend process, policy, procedure, or protocol revisions when warranted.

Standards of Professional Performance for Clinical Research Nursing

Standard 7. Ethics

The clinical research registered nurse practices ethically.

Competencies

The clinical research registered nurse:

- Integrates the Code of Ethics for Nurses with Interpretive Statements (ANA, 2015) to guide nursing practice and articulate the moral foundation of nursing.
- Practices with compassion and respect for the inherent dignity, worth, and unique attributes of all people.
- Advocates for research participants' rights to informed decision-making and self-determination.
- Seeks guidance in situations where the rights of the individual conflict with public health guidelines or research protocol related activities.
- Endorses the understanding that the primary commitment is to the research participant regardless of setting or situation, with a focus on the core principles and guidelines for research involving human subjects.
- Maintains therapeutic relationships and professional boundaries.
- Advocates for the rights, health, and safety of the research participant and others.
- Safeguards the privacy and confidentiality of research participants, others, and their data and information within ethical, legal, and regulatory parameters.
- Demonstrates professional accountability and responsibility for nursing practice.
- Maintains competence though continued personal and professional development.
- Demonstrates commitment to self-reflection and self-care.
- Contributes to the establishment and maintenance of an ethical environment that is conducive to safe, quality health care that maintains fidelity to the research protocol.
- Advances the profession through scholarly inquiry, professional standards development,

and the generation of policy.

- Collaborates with other health professionals and the public to protect human rights, promote health diplomacy, enhance cultural sensitivity and congruence, and reduce health disparities.

- Articulates nursing values to maintain personal integrity and the integrity of the profession.

- Integrates principles of social justice into nursing policy.

Standard 8. Culturally Congruent Practice

The clinical research registered nurse practices in a manner that is congruent with cultural diversity and inclusion principles.

Competencies

The clinical research registered nurse:

- Demonstrates respect, equity, and empathy in actions and interactions with all research participants.
- Participates in life-long learning to understand cultural preferences, worldview, choices, and decision-making processes of diverse participants.
- Creates an inventory of one's own values, beliefs, and cultural heritage.
- Applies knowledge of variations in health beliefs, practices, and communication patterns in all nursing practice activities.
- Identifies the stage of the research participant's acculturation and accompanying patterns of needs and engagement.
- Considers the effects and impact of discrimination and oppression on practice within and among vulnerable populations and cultural groups.
- Uses skills and tools that are appropriately vetted for the culture, literacy, and language of the population served.
- Communicates with appropriate language and behaviors, including the use of medical interpreters and translators in accordance with research participant's preferences and research regulations.
- Identifies the cultural-specific meaning of interactions, terms and content.
- Respects potential research volunteer or participant decisions based on age, tradition, belief and family influence, and stage of acculturation.
- Advocates for research-specific policies that promote health and prevent harm among culturally diverse, under-served/under-represented, or vulnerable populations.
- Promotes equal access to services, tests, interventions, health promotion programs, enrollment in research, education, and other opportunities.

- Educates nurse colleagues and other professional about cultural similarities and differences of research participants, families, groups, communities, and populations.
- Develops recruitment and retention strategies to achieve a multicultural study population.
- Ensures that the communities engaged in research receive equal transfer of knowledge and benefit.

Additional competencies for the graduate-level prepared clinical research nurse, including the APRN

The graduate-level prepared clinical research nurse or the APRN:

- Evaluates tools, instruments, and service provided to culturally diverse and populations considered vulnerable in research.
- Advances organizational policies, programs, services, and practices that reflect respect, equity, and values for diversity and inclusion.
- Engages research participants, key stakeholders, and others in designing and establishing internal and external cross-cultural partnerships.
- Conducts research to improve health care and healthcare outcomes for culturally diverse populations.
- Develops recruitment and retention strategies to achieve a multicultural workforce.
- Promotes shared decision-making solutions in planning, prescribing, and evaluating processes when the research participant's cultural preferences and norms may create incompatibility with evidence-based practice or the research protocol.
- Leads interprofessional teams to identify the cultural and language needs of the research participant.

Standard 9. Communication

The clinical research registered nurse communicates effectively in all areas of practice.

Competencies

The clinical research registered nurse:

- Assesses one's own communication skills and effectiveness.
- Demonstrates cultural empathy when communicating.
- Assesses communication ability, health literacy, resources, and preferences of research participants to inform the interprofessional team and others.
- Uses language translation resources to ensure effective communication.
- Incorporates appropriate alternative strategies to communicate effectively with research participants who have visual, speech, language, or communication difficulties.
- Uses communication styles and methods that demonstrate caring, respect, deep listening, authenticity, and trust.
- Conveys accurate information.
- Maintains communication with the interprofessional team and others to facilitate safe transitions and continuity in care delivery and research protocol activities.
- Contributes the clinical research nursing perspective in interactions with others and discussions with the interprofessional team.
- Exposes care processes and research protocol decisions that do not appear to be in the best interest of the research participant.
- Discloses concerns related to potential or actual hazards and errors in care, research related activities, or the practice environment to the appropriate level.
- Demonstrates continuous improvement of communication skills.
- Appropriately communicates research protocol information to the research participant, family, interprofessional team, and others.

Additional competencies for the graduate-level prepared clinical research nurse, including the APRN

The graduate-level prepared clinical research nurse or the APRN:

- Assumes a leadership role in shaping environments that promote healthy communication.

Standard 10. Collaboration

The clinical research registered nurse collaborates with the research participant and other key stakeholders in the conduct of nursing practice.

Competencies

The clinical research registered nurse:

- Identifies the areas of expertise and contribution of other professionals and key stakeholders.
- Clearly articulates the CRN's role and responsibilities within the clinical and research team.
- Uses the unique and complementary abilities of all members of the health care team to optimize attainment of desired healthcare and research outcomes.
- Partners with the research participant and key stakeholders to affect change, leading to positive healthcare and research outcomes and quality care.
- Uses appropriate tools and techniques, including information systems and technologies, to facilitate discussion and research team functions, in a manner that protects dignity, respect, privacy, and confidentiality.
- Promotes engagement through consensus-building and conflict management.
- Uses effective group dynamics and strategies to enhance health care team performance.
- Exhibits dignity and respect when interacting with others and giving/receiving feedback.
- Partners with all stakeholders to create, implement, and evaluate a comprehensive health care and research plans.

Additional competencies for the graduate-level prepared clinical research nurse, including the APRN

The graduate-level prepared clinical research nurse or the APRN:

- Participates in interprofessional activities, including but not limited to education, consultation, management, technological development, or research to enhance outcomes.

- Provides leadership for establishing, improving, and sustaining collaborative relationships to achieve safe, quality care for research participants, while ensuring the integrity of the research protocol.

- Advances interprofessional healthcare and research plan-of-care documentation and communications, rationales for plan-of-care changes, and collaborative discussions to improve research participant outcomes and maintain fidelity to the research protocol.

Standard 11. Leadership

The clinical research registered nurse leads within the professional practice setting and the profession**.**

Competencies

The clinical research registered nurse:

- Contributes to the establishment of an environment that supports and maintains respect, trust, and dignity.
- Encourages innovation in practice and role performance to attain personal and professional plans, goals, and vision.
- Communicates to manage change and address conflict.
- Mentors colleagues for the advancement of nursing practice and the profession to enhance safe, quality health care within the unique framework of the research environment.
- Retains accountability for delegated nursing care given to the research participant.
- Contributes to the evolution of the profession through participation in professional organizations.
- Influences policy to promote health.
- Articulates the professional role of the CRN to others.
- Supports a culture where systems are monitored and evaluated to improve the quality of clinical research.

Additional competencies for the graduate-level prepared clinical research nurse, including the APRN

The graduate-level prepared clinical research nurse or the APRN:

- Influences decision-making bodies to improve the professional practice environment and the research participant outcomes.
- Enhances the effectiveness of the interprofessional team.

- Promotes advanced practice nursing and role development by interpreting its roles for research participants and policymakers.
- Models expert practice to interprofessional team members and research participants.
- Mentors colleagues in the acquisition of clinical research nursing knowledge, skills, abilities, and judgment.

Standard 12. Education

The clinical research registered nurse seeks knowledge and competency that reflects current clinical research nursing practice and promotes futuristic thinking.

Competencies

The clinical research registered nurse:

- Identifies learning needs based on nursing knowledge and the various roles that a CRN may assume.
- Participates in ongoing educational activities related to appropriate knowledge bases and professional issues.
- Mentors CRNs new to their roles for the purpose of ensuring successful enculturation, orientation, and emotional support.
- Supports acculturation of nurses new to their clinical research roles by role modeling, encouraging, and sharing pertinent information relative to optimal care delivery and the conduct of clinical research.
- Demonstrates a commitment to lifelong learning through self-reflection and inquiry for learning and personal growth.
- Seeks experiences that reflect current practice to maintain and advance knowledge, skills, abilities, attitudes, and judgment in clinical practice or role performance as a CRN.
- Acquires knowledge and skills relative to the clinical research role, population, specialty, setting, and global or local health situation.
- Participates in formal consultations or informal discussions to address issues in clinical research nursing practice as an application of education and knowledge base.
- Identifies modifications or accommodations needed in the delivery of education based on the research participants' and family members' needs.
- Shares educational findings, experiences, and ideas with peers.
- Facilitates a work environment supportive of ongoing education of healthcare professionals.
- Maintains professional portfolio that provide evidence of individual competence and lifelong learning.

Standard 13. Evidence-based Practice and Research

The clinical research registered nurse integrates evidence and research finding into practice.

Competencies

The clinical research registered nurse:

- Articulates the values of research and its application relative to the healthcare setting, research protocol, and practice.
- Identifies questions in the healthcare setting, research protocol, and practice that can be answered by nursing research.
- Uses current evidence-based nursing knowledge, including research findings, to guide practice within parameters of the research protocol.
- Incorporates evidence when initiating changes in nursing practice.
- Participates in the formulation of evidence-based practice through research.
- Promotes ethical principles of research in practice and the healthcare setting.
- Appraises nursing research for optimal application in practice and the healthcare setting.
- Shares peer-reviewed research findings with colleagues to integrate knowledge into nursing practice.

Additional competencies for the graduate-level prepared clinical research nurse, including the APRN

The graduate-level prepared clinical research nurse or the APRN:

- Integrates research-based practice in all settings within parameters of the research protocol.
- Uses current healthcare research findings and other evidence to expand knowledge, skills abilities, and judgment; to enhance role performance; and to increase knowledge of professional issues.
- Uses critical thinking skills to connect theory and research to practice.
- Integrates nursing research to improve quality in nursing practice.

- Contributes to nursing knowledge by conducting or synthesizing research and other evidence that discovers, examines, and evaluates current practice, knowledge theories, criteria, and creative approaches to improve outcomes for research participants.
- Encourages other nurses to develop research skills.
- Performs rigorous critique of evidence derived from databases to generate meaningful evidence for nursing practice.
- Advocates for the ethical conduct of research and translational scholarship with particular attention to the protection of the research participant.
- Promotes a climate of collaborative research and clinical inquiry.
- Disseminates research findings through activities such as presentations, publications, consultation, and journal clubs.

Standard 14. Quality of Practice

The clinical research registered nurse contributes to quality nursing practice.

Competencies

The clinical research registered nurse:

- Ensures that nursing practice is safe, effective, efficient, equitable, timely, and patient-centered (IOM, 1999; IOM, 2001).
- Identifies barriers and opportunities to improve research protocol adherence, healthcare safety, effectiveness, efficiency, equitability, timeliness, and patient-centeredness.
- Recommends strategies to improve nursing quality and operationalization of required protocol activities.
- Uses creativity and innovation to enhance nursing care and the conduct of clinical research.
- Participates in quality improvement.
- Collects data to monitor the quality of nursing practice and adherence to the research protocol.
- Contributes in efforts to improve health care efficiency, research participant safety, adherence to the research protocol, and accurate data collection.
- Provides critical review and/or evaluation of policies, procedures, and guidelines to improve the quality of health care, research participant safety, adherence to the research protocol, accurate data collection, and the conduct of clinical research.
- Engages in formal and informal peer review processes.
- Collaborates with the interprofessional team to implement quality improvement plans and interventions within parameters of the research protocol.
- Documents nursing practice and protocol activities in a manner that supports quality and performance improvement initiatives.
- Achieves professional certification, when available.

Additional competencies for the graduate-level prepared clinical research nurse, including the APRN

The graduate-level prepared clinical research nurse or the APRN:

- Analyzes trends in healthcare quality data, including examination of cultural influences and factors.
- Incorporates evidence into nursing practice to improve outcomes within parameters of the research protocol.
- Designs innovations to improve outcomes for research participants.
- Provides leadership in the design and implementation of quality improvement initiatives.
- Promotes a practice environment that supports evidence-based health care.
- Contributes to nursing and interprofessional knowledge through scientific inquiry.
- Encourages professional or specialty certification.
- Engages in development, implementation, evaluation, and/or revision of policies, procedures, and guidelines to improve healthcare quality, human subjects protection, adherence to the research protocol.
- Uses data and information in system-level decision making.
- Influences the organizational system to improve outcomes.

Additional competencies for the advanced practice registered nurse:

- Engages in comparison evaluations of the effectiveness and efficacy of diagnostic tests, clinical procedures and therapies, and treatment plans, in partnership with research participant, to optimize health and healthcare quality.
- Designs quality improvement studies, research initiatives, and programs to improve health outcomes in diverse settings.
- Applies knowledge obtained from advanced preparation, as well as current research and evidence-based information, to clinical decision-making at the point of care to achieve optimal health within parameters of the research protocol.
- Uses available benchmarks as a means to evaluate practice at the individual, departmental, or organizational level.

Standard 15. Professional Practice Evaluation

The clinical research registered nurse evaluates one's own and others' nursing practice.

Competencies

The clinical research registered nurse:

- Engages in self-reflection and self-evaluation of nursing and research practice on a regular basis, identifying areas of strength as well as areas in which professional growth would be beneficial.

- Adheres to the guidance about professional practice as specified in the *Nursing Scope and Standards of Practice* and the *Code of Ethics for Nurses with Interpretive Statements.*

- Ensures that nursing practice is consistent with regulatory requirements pertaining to licensure, relevant statues, rules, regulations, and conduct of clinical research.

- Uses organizational policies, procedures, and research protocol requirements to guide professional practice.

- Influences organizational policies and procedures and research protocol requirements to promote interprofessional evidence-based processes.

- Provides evidence for practice decisions and actions as part of the formal and informal evaluation processes.

- Seeks formal and informal feedback regarding one's own practice from research participants, peers, colleagues, supervisors, and others.

- Provides peers and others with formal and informal constructive feedback regarding their practice or research role performance.

- Takes action to achieve goals identified during the evaluation process.

Standard 16. Resource Utilization

The clinical research registered nurse utilizes appropriate resources to plan, provide, and sustain evidence-based nursing services that are safe, effective, and fiscally responsible.

Competencies

The clinical research registered nurse:

- Assesses individual research participant care needs, research protocol requirements, and resources available to achieve desired participant and research outcomes.
- Assists the research participant and family in factoring costs, risks, and benefits in decisions about standard treatment and care or participation in clinical research.
- Assists the research participant in identifying and securing appropriate services to address needs across the healthcare continuum.
- Delegates elements of care and research activities to appropriate healthcare workers and research providers in accordance with applicable legal and policy parameters.
- Identifies the impact of resource allocation on the potential for harm, complexity of the task, and desired outcomes in the conduct of clinical research.
- Advocates for resources that enhance nursing and research practice.
- Integrates telehealth and mobile health technologies into practice to promote positive interactions between research participants and care providers in the conduct of clinical research.
- Uses organizational and community resources to implement interprofessional plans and research plans.
- Addresses discriminatory healthcare practices and the impact on resource allocation.

Additional competencies for the graduate-level prepared clinical research nurse, including the APRN

The graduate-level prepared clinical research nurse or the APRN:

- Designs innovative solutions for research participant care problems that use resources effectively, maintain quality of care, and promote research protocol integrity.
- Creates evaluation strategies that address cost-effectiveness, cost-benefit, and efficiency factors associated with nursing practice and research protocol requirements.

- Assumes complex and advanced leadership roles to initiate and guide change.
- Engages organizational and community resources to formulate and implement interprofessional plans of care and research activities.
- Determines feasibility of the research protocol and devises innovative approaches to implementation that use resources effectively and maintain quality.

Standard 17. Environmental Health

The clinical research registered nurse practices in an environmentally safe and healthy manner.

Competencies

The clinical research registered nurse:

- Promotes a safe, healthy workplace and practice environment.
- Uses environmental health concepts in practice.
- Assesses the environment to identify risk factors.
- Reduces environmental health risks to self, colleagues, and research participants.
- Communicates information about environmental health risk and exposure reduction strategies.
- Advocates for the safe, judicious, and appropriate use of research agents/products.
- Collaborates with the interprofessional team to identify and decrease exposure to research agents/products and the possibility of unknown side effects.
- Incorporates technologies to promote safe practice environments.
- Uses products or treatments consistent with evidence-based practice to reduce environmental threats.
- Participates in developing strategies to promote healthy communities and practice environments.

Additional competencies for the graduate-level prepared clinical research nurse, including the APRN

The graduate-level prepared clinical research nurse or the APRN:

- Analyzes the impact of social, political, and economic influences on the global environment and human health experience.
- Creates partnerships that promote sustainable global environmental health policies and conditions that focus on prevention of hazards to people and the natural environment (ANA 2007).

Glossary

Common terms used in clinical research nursing practice. Definitions obtained and adapted from CenterWatch (n.d.), NIH Clinical Trials (n.d.), and NIH Grants and Funding (n.d.).

Adverse Event (AE)

A negative experience encountered by an individual during the course of a clinical trial. An AE can include previously undetected symptoms or the exacerbation of a pre-existing condition. When an AE has been determined to be related to the investigational product, it is considered an Adverse Drug Reaction.

Assent

A child's affirmative agreement to participate in a clinical investigation. Mere failure to object may not, absent affirmative agreement, be construed as assent.

Belmont Report

A report created by the former United States Department of Health, Education, and Welfare (which was renamed to Health and Human Services) entitled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," authored by Dan Harms. The report was created on April 18, 1979, and gets its name from the Belmont Conference Center where the document was drafted. This is an important historical document in the field of medical ethics and continues as an essential reference for institutional review boards that review HHS-conducted or HHS-supported human subjects research proposals involving human subjects, in order to ensure that the research meets the ethical foundations of the regulations.

Child

The NIH Policy on Inclusion of Children defines a child as an individual under the age of 21 years. The intent of the NIH policy is to provide the opportunity for children to participate in research studies when there is a sound scientific rationale for including them, when their participation benefits children, and when it is appropriate under existing Federal guidelines. Thus, children must be included in NIH conducted or supported clinical research unless there are scientific or ethical reasons not to include them.

DHHS Regulations (45 CFR part 46, Subpart D, Sec.401-409) provide additional protections for children involved as subjects in research, based on this definition: "Children are persons who have not attained the legal age for consent to treatments or procedures involved in research, under the applicable law of the jurisdiction in which the research will be conducted." Generally, state laws define what constitutes a "child." Consequently, the age at which a child's own consent is required and sufficient to participate in research will vary according to state law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

See Common Rule definition of research at 45 CFR 46.102(d).

See Common Rule definition of human subject at 45 CFR 46.102(f).

The term "prospectively assigned" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of the clinical trial.

An *intervention* is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related processes and/or endpoints. Examples include, but are not limited, to drugs/small molecules/compounds, biologics, devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); and treatment, prevention, and diagnostic strategies.

A *health-related biomedical or behavioral outcome* is defined as the pre-specified effect of an intervention on the study subjects. Examples include positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and/or information retention); disease processes; health-related behavior; and well-being or quality of life

Biomedical clinical trials of an experimental drug, treatment, device, or behavioral intervention may proceed through four phases:

Phase I. Tests a new biomedical intervention in a small group of people (e.g. 20-80) for the first time to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects).

Phase II. Study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and further evaluate safety.

Phase III. Study to determine efficacy of the biomedical or behavioral intervention in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions, as well as to monitor adverse effects and to collect information that will allow the interventions to be used safely.

Phase IV. Studies conducted after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

Clinical Research

Defined as research with human subjects that is:

- Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes:
    - mechanisms of human disease
    - therapeutic interventions
    - clinical trials
    - development of new technologies
- Epidemiological and behavioral studies.
- Outcomes research and health services research.

Code of Federal Regulations (CFR)
The codified regulations of the Federal government based on the final agency regulations published in the Federal Register.

Common Rule
1991 agreement to cover all federal-sponsored research by a common set of regulations.

Consent Form
A document explaining all relevant study information to assist the study volunteer in understanding the expectations and requirements of participation in a clinical trial. This document is presented to and signed by the study subject.

Control Group
A comparison group of study subjects who are not treated with the investigational agent. The subjects in this group may receive no therapy, a different therapy, or a placebo. These subjects may be healthy volunteers or patients with a medical diagnosis.

Data and Safety Monitoring Plan

For each NIH-supported clinical trial, NIH requires a data and safety monitoring plan that will provide oversight and monitoring to ensure the safety of participants and the validity and integrity of the data. The level of monitoring should be commensurate with the risks and the size and complexity of the clinical trial. A detailed data and safety monitoring plan must be submitted to the applicant's IRB and subsequently to the awarding IC for approval prior to the accrual of human subjects.

Food and Drug Administration (FDA)
Within the Department of Health and Human Services. Enforces Food, Drug and Cosmetics Act and related federal public health laws. Grants IND, IDE, PMA and NDA approvals.

Good Clinical Practice (GCP)

International ethical and scientific quality standard for designing, conducting, monitoring, recording, auditing, analyzing, and reporting studies. Insures that the data reported is credible and accurate, and that subjects' rights and confidentiality are protected.

Healthy Patient Studies

Most healthy patient studies are Phase I studies, primarily concerned with assessing a drug's safety. This initial phase of testing in humans is done in a small number of healthy volunteers who are usually paid for participating in the study. Other healthy patient studies investigate the effects of environmental conditions on healthy volunteers. For instance, the studies may investigate the effects of exercise, vitamins, or diet on the human body. (Also refer to Control Group.)

Human Subject

A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information. Regulations governing the use of human subjects in research extend to use of human organs, tissues, and body fluids from identifiable individuals as human subjects and to graphic, written, or recorded information derived from such individuals. (See Public Policy Requirements and Objectives-Human Subjects Protection.)

Informed Consent

Person's voluntary agreement, based upon adequate knowledge and understanding, to participate in human subjects research or undergo a medical procedure. In giving informed consent, people may not waive legal rights or release or appear to release an investigator or sponsor from liability for negligence. Go to 21 CFR 50.20 and 50.25.

Institutional Review Board (IRB)

An administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the organization with which it is affiliated. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction.

Participant: A person who volunteers to participate in a research study. A participant may be a patient, an individual with a chronic or acute medical or mental health condition, or a healthy volunteer.

Placebo

An inactive substance designed to resemble the drug being tested. It is used as a control to rule out any psychological effects of testing that may present. Most well-designed studies include a control group that is unwittingly taking a placebo.

Privacy Act

The Privacy Act of 1974, 5 U.S.C. 552a (as amended), and its implementing regulations (45 CFR part 5b) provide certain safeguards for information about individuals maintained in a system of records (i.e., information may be retrieved by the individual's name or other identifying

information). These safeguards include the rights of individuals to know what information about them is maintained in Federal agencies' files (hard copy or electronic) and how it is used, how they may obtain access to their records, and how to correct, amend, or request deletion of information in their records that is factually incorrect. Records maintained by NIH with respect to grant applications, grant awards, and the administration of grants are subject to the provisions of the Privacy Act.

Protocol
A detailed plan that sets forth the objectives, study design, and methodology for a clinical trial. A study protocol must be approved by an IRB before investigational drugs may be administered to humans.

Randomization
Study participants are usually assigned to groups in such a way that each participant has an equal chance of being assigned to either treatment or control group. Since randomization ensures that no specific criteria are used to assign any patients to a particular group, all the groups will be equally comparable.

Recruitment
Act of enrolling subjects with the proper inclusion criteria.

Serious Adverse Event (SAE)
Any adverse event (AE) that is fatal, life-threatening, permanently disabling, or that results in hospitalization, initial or prolonged.

Standards of Care
Treatment regimen or medical management based on state-of-the-art participant care.

Subject/Study Subject
Participant in a study. See "Human Subject".

Therapeutic Misconception
The tendency for research participants to minimize or ignore the risks posed to their own well-being by participation due to a deeply held and nearly unshakeable conviction that every aspect of their participation in research has been designed for their own individual benefit (Emanuel, 2003).

Vulnerable Subjects
Individuals (or groups of individuals) who cannot give informed consent because of limited autonomy (e.g., children, mentally ill, and prisoners). Also refers to subjects who may be unduly influenced to participate (e.g., students, subordinates and patients).

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