Oncology Clinical Trials Nurse Competencies

Project Team Members

Penny Daugherty, RN, MS, OCN®, Co-Leader
Director of Clinical Research
Southeastern Gynecologic Oncology
Atlanta, Georgia

Linda Schmieder, MSN, RN, CCRC, Co-Leader
Director, Study Implementation
Clinical Research Services
Roswell Park Cancer Institute
Buffalo, New York

Marjorie Good, RN, BSN, MPH, OCN®
Manager
Wichita Community Clinical Oncology Program
Wichita, Kansas

David Leos, RN, BSN, MBA, OCN®, CCRA
Oncology Clinical Educator
Memorial Hermann Southwest Hospital
Houston, Texas

Patricia Weiss, RN, MSN, OCN®, CCRP
Clinical Research Coordinator
Cleveland Clinic Foundation
Cleveland, Ohio

Oncology Nursing Society Staff

Heather Belansky, RN, MS
Project Manager, Education Team
Oncology Nursing Society
Pittsburgh, Pennsylvania

Barbara Lubejko, RN, MS
Project Manager, Education Team
Oncology Nursing Society
Pittsburgh, Pennsylvania
Expert Reviewers

Rose Ermete, RN, BSN, OCN®, CCRP
Research Nurse Coordinator
Michigan Cancer Research Consortium, CCOP
St. Mary Mercy Hospital
Livonia, Michigan

Kristen Fessele, RN, MSN, AOCN®
Research Associate
Oncology Nursing Society
Pittsburgh, Pennsylvania

Bertie Ford, RN, MS, AOCN®
Clinical Oncology Specialist
Genentech BioOncology
Westerville, Ohio

Denise Friesema, MS, RN, OCN®
Director, Clinical Research Operations
Section of Hematology/Oncology
University of Chicago Medical Center
Chicago, Illinois

Angela Klimaszewski, RN, MSN
Technical Content Editor, Publications Team
Oncology Nursing Society
Pittsburgh, Pennsylvania

Cheryl D. Kosits, RN, MSN
Nurse Case Manager
Moores UCSD Cancer Center
San Diego, California

Patricia McLaughlin, RN, MSN, AOCN®, CCRP
Senior Research Nurse
Cancer Treatment Centers of America
Eastern Regional Medical Center
Philadelphia, Pennsylvania

Elizabeth Ness, RN, MS
Director of Staff Development
Center for Cancer Research
National Cancer Institute
Bethesda, Maryland

Rose Mary Padberg, RN, MA
Clinical Trials Support Coordinator
Office of Communication and Education
National Cancer Institute
Rockville, Maryland

Debra Wujcik, RN, PhD, AOCN®
Director, Clinical Trials at Meharry
Vanderbilt Ingram Cancer Center
Associate Professor of Nursing
Vanderbilt University School of Nursing
Nashville, Tennessee

Joyce Yasko, PhD, RN
Vice President, Clinical Research Administration and Services
Roswell Park Cancer Institute
Buffalo, New York
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Overview

Key Terms Used in This Document

- **Clinical trials:** The scientific process used to evaluate new interventions or new indications for previously approved interventions. An intervention should address a specific question. Access to the intervention may be restricted to clinical trial participants.
- **Clinical trials nurse (CTN):** The specialty nursing role requiring a unique framework of knowledge for working with patients involved in clinical research trials. The CTN role has multiple names in diverse practices, including *clinical trials coordinator, clinical research nurse*, and *protocol coordinator*.
- **Novice:** A nurse who has worked two years or less as a CTN and is building upon his or her academic preparation, nursing knowledge, and oncology experience to develop expertise in the oncology CTN role.
- **Patient:** Defined in the clinical trial setting as a participant in the clinical trial process who is under the specialized care of a CTN or in a specific relationship with the nurse based on clinical trial requirements. Synonyms for *patient* in this setting include *client, subject, and participant*.

Context of Cancer Clinical Trials

An estimated 1.5 million (1,479,350) new cancer cases are expected to be diagnosed in the United States in 2009, with more than 562,000 deaths projected (American Cancer Society [ACS], 2009). However, it is important to note that the five-year survival rate for all cancers has improved significantly from 50% for cancers diagnosed between 1975 and 1977 to 66% for those detected between 1996 and 2004 (ACS). This improvement in survival rate reflects the progress made in the diagnosis of certain cancers at earlier stages as well as improvements in treatment.

Clinical trials are essential for the identification of new, more effective therapies and have played a significant role in producing advances in disease prevention, treatment, and rehabilitation for many diseases, including cancer (Comis, Miller, Aldige, Krebs, & Stoval, 2003; Murthy, Krumholz, & Gross, 2004). In addition, because many adult cancer therapies result in disease control as opposed to cure, it is imperative for the scientific community to engage in clinical trials to improve outcomes such as survival, side effect profiles, combination therapies, and quality of life (C-Change & Coalition of Cancer Cooperative Groups, 2007).

These advances in cancer care and the development of more effective cancer therapeutics depend largely on an effective clinical trial process. As of October 2009, the National Cancer Institute Physician Data Query (PDQ®), which includes the world’s most comprehensive cancer clinical trials registry, includes abstracts of more than 8,000 clinical trials that are open and active for patient accrual, including trials for cancer treatment, genetics, diagnosis, supportive care, screening, and prevention. The PDQ includes trials sponsored by the National Cancer Institute and also many clinical trials sponsored by pharmaceutical companies, medical centers, and other groups from around the world.

The development and testing of a new drug takes an average of 12 years. The drug discovery process, including target discovery, lead compound identification, optimization of chemical and pharmaceutical properties, and efficacy and safety assessment, takes an average of four to five years (U.S. Congress, 2006). Following an additional phase of preclinical development devoted to further detailed safety assessment, the drug must be examined using a series of formal, meticulous clinical protocols so that its clinical safety and effectiveness can be proved with statistical validity (Kurzrock et al., 2009). The average successfully developed new molecular agent requires 7.5 years for completion of these clinical trials and U.S. Food and Drug Administration approval after its preclinical evaluation (DiMasi, Hansen, & Grabowski, 2003; U.S. Congress).

Background

The effective conduct of cancer clinical trials requires the involvement of a variety of personnel. The specific types of personnel involved at an individual institution will depend on the requirements of the trials and the resources of the institution. The Oncology Nursing Society (ONS) believes that oncology nurses are essential to the effective conduct of cancer treatment and prevention trials. In particular, ONS has taken the position that the “coordination of clinical trials (e.g., coordination of clinical sites, development of standardized treatment orders, symptom management, patient education and advocacy, facilitation of informed consent, assistance with participant accrual and retention) is accomplished best by RNs who have been educated and certified in oncology nursing” (ONS, 2009).
A growing number of ONS members identify clinical research as their primary job focus. With the dominant influence of clinical research in oncology, it is understandable that clinical trials nursing has developed a mainstream standing in oncology, perhaps more than in other disease areas. Deininger (2008) noted that “while oncology nursing has its origins in the pursuit of the magic bullet, clinical trials nursing also is grounded in the pursuit of inquiry” (p. 353). Today’s oncology nurse clinicians have insight into the clinical trial process as it pertains to the study participants in whose care they may be involved. Those same clinicians may decide to enter the research subspecialty of oncology and impart an added value to the research team by applying the basic nursing tenets of clinical and critical-thinking skills, bedside experience, interpersonal skills, and patient advocacy.

The coordination of clinical trials can most effectively be performed by a clinical trials nurse (CTN). As a licensed professional nurse, the CTN brings a background of scientific knowledge, critical-thinking skills, and understanding of individual and group behavior. In particular, the CTN brings the ability to

- Anticipate physiologic and psychosocial problems and prepare for them using evidence-based nursing expertise.
- Recognize the potential impact of study outcomes on standards of oncology care.
- Assess for protocol-related needs and identify applicable resources.
- Recognize at-risk groups and individuals.
- Incorporate the nursing process into holistic patient care, including clinical assessment to identify needs and problems experienced by patients and their caregivers.
- Understand how scientifically based interventions work.
- Provide patient, caregiver, and colleague education.
- Advocate for patients and help them navigate through complicated systems.
- Form and maintain productive collegial relationships with all research team members, recognizing the value of what each contributes to the successful execution of clinical trials.
- Interact with case managers, discharge planners, and referral agencies using nursing knowledge of healthcare systems to facilitate transitions between care settings and home.

Evidence is beginning to support how CTN involvement in clinical trials can improve clinical trial and patient outcomes. Anecdotal data from O’Halloran, Curl, Hagen, and Sveningson (as cited in Pitler et al., 2009) suggest that the involvement of CTNs in research is associated with improved quality of communication, as well as increased recruitment of participants and improved protocol adherence to cancer protocols. For instance, CTNs can apply their unique expertise to

- Help identify qualified patients for studies, recognizing those who may not be able to complete a study for reasons that might not be evident in the protocol.
- Identify trends in side effects and work with the principal investigator to develop and evaluate patient management strategies.
- Effectively interface with study participants, related caregivers, investigators, ancillary research staff, primary care physicians or their staff, and sponsors.

Purpose of Competency Development

The ONS CTN Core Competencies were developed in response to verbalized needs from ONS members for a comprehensive curriculum on clinical trials and standardization of role expectations. The critical nature of nurses’ roles in clinical trials, as well as the value of clinical trials in cancer care, led to an ONS Steering Council plan for the development of CTN competencies as well as a Clinical Trials 101 webcourse.

The ONS CTN Core Competencies are intended to provide a listing of the fundamental knowledge and skills that novice oncology CTNs should possess or acquire during their first one to two years in the role. These competencies are meant to reflect practice across the majority of settings but must be considered within the context of the individual research program. However, there is a desire to define a minimum standard of practice going forward.

Several challenges arose during the development of these competencies. First, there is significant diversity in clinical background and educational preparation of professional nurses who go into the specialty of clinical trials nursing, leading to a great variability of skills and knowledge brought to the role. Second, the manner in which the CTN role is operationalized varies greatly from setting to setting. Novice CTNs practicing in settings with more resources (personnel and material) tend to have a role more limited to the clinical aspects of managing a clinical trial patient, with other nonclinical competencies being beyond their scope. Alternately, CTNs who work in a setting with fewer resources tend
to operate in a more generalist mode with a larger range of tasks, including more administrative responsibilities. Additionally, there is a lack of a standardized approach to orientation and development of CTNs. In many cases, the CTN must learn on the job. Many new CTNs must bear the responsibility for identifying their baseline knowledge and skill level, recognizing professional development needs, and locating resources to meet these learning needs. Finally, the role of the CTN has evolved significantly in the past few years as CTNs have broadened their focus in response to the changing economic and regulatory milieu. Today’s CTNs are expected to utilize a myriad of skills, so a comprehensive understanding of the multidimensional role is crucial to individual success.

**Definition of Oncology Clinical Trials Nurse Core Competencies**

The Oncology CTN Core Competencies include the fundamental knowledge, skills, and expertise required to proficiently (a) identify and care for participants in clinical trials with a past, current, or potential diagnosis of cancer, (b) manage oncology clinical trials in diverse settings, (c) ensure protection of subjects enrolled in clinical trials, and (d) ensure that scientific integrity is maintained through data reliability and strict adherence to regulatory mandates.

**Mission and Core Values**

Clinical trials are the basis for advancement in oncology knowledge and treatment. Scientific rigorousness and integrity are essential for the advancement of this knowledge. CTNs are in a unique role to contribute to the scientific process through collection of quality data and nursing care of trial participants. Recognizing the diversity of settings and backgrounds that CTNs bring to the research role, this mission statement provides a unifying framework for the core values essential to the knowledge base and skill set of CTNs.

The mission of the Clinical Trials Competency Project is to delineate the core values, skills, knowledge, and expertise required to become proficient as an oncology CTN, highlighting the unique contribution that nurses, and the nursing process, bring to clinical trials practice.

Core values of the role require that CTNs

- Advocate for patient safety and trial integrity.
- Advance evidence-based oncology care through scientifically sound research.
- Recognize the unique value that professional nurses contribute to the successful conduct and outcomes of clinical trials.

**Process of Competency Development**

The Oncology CTN Core Competencies were developed using a three-step process chosen after reviewing the literature describing the development of competencies for the ONS (2008) *Oncology Clinical Nurse Specialist Competencies*, the ONS (2007) *Oncology Nurse Practitioner Competencies*, and the American Nurses Association (2005) *Essential Nursing Competencies and Curricula Guidelines for Genetics and Genomics*.

**Step 1: Develop List of Core Competencies**

The first competency statement draft was developed using information from a variety of sources. Several documents were reviewed for skill and knowledge requirements, including the ONS *Manual for Clinical Trials Nursing* (Klimaszewski, Bacon, Deininger, Ford, & Westendorp, 2008a), position descriptions, the clinical trials education modules on the ONS Clinical Trials Nursing Special Interest Group (CTN SIG) Virtual Community, curricula from schools of nursing with research management programs, and cooperative group training manual outlines. This information was expanded upon and further detailed during project team brainstorming sessions.

In addition, an open-ended questionnaire was developed to solicit input about the essential knowledge, skills, and expertise required of a novice oncology CTN. A sample was drawn from members of the CTN SIG, ONS members who had previously expressed interest in developing the core competencies, and members of the clinical trials initiative leadership group. Ninety surveys were sent and 19 responses were received (21% response rate), reflecting a diversity of roles, practice settings, trial type, experience level (2–24 years of experience in clinical trials with an average of 12 years), and personal expectations for the CTN role. The responses varied widely related to roles, required skills, and knowledge.

From this information, the project team defined role categories and developed listings of specific behaviors required to support each category.
Step 2: Field Review

Field reviewers were asked to comment on the clarity of the draft competency statements and whether these behaviors and skills were core to the role of the CTN. They were also asked to provide input on whether each statement should be included in the final ONS CTN Core Competencies document and to suggest other competencies that might be included.

The field review survey was sent to all CTN SIG members as well as other ONS members who listed their primary position as a CTN. Of the 1,617 surveys sent out, 247 responses were received (15% response rate). The respondents represented all regions of the country (44 states) and a wide variety of practice settings. They varied in experience level, with 61% having more than six years of experience as a CTN. Significant diversity also existed in educational preparation, ranging from diploma program graduates to doctorally prepared nurses, with 50% holding a BSN as their highest nursing degree. They reported involvement with all types and phases of clinical trials from cooperative groups, industry, and individual institutions.

Based upon the field reviewers’ ratings of each statement as well as individual comments, the list of core competencies was heavily edited to clarify individual statements, reduce redundancy, and eliminate competencies that were deemed beyond the scope of novice CTNs.

Step 3: Expert Review

Eleven expert reviewers were identified and agreed to complete a review of the CTN core competencies. These experts were chosen based upon their years of experience and leadership roles in clinical trials nursing. The expert reviewers were asked to comment on the flow, clarity, completeness, and appropriateness of the overall competency listing, as well as to provide any further feedback on the individual statements. Based upon the feedback of the expert reviewers, the project team developed the final version of the CTN core competency listing found in this document.

Applicability and Dissemination

The intent of the development of these core competencies is not only to develop the framework for defining what a novice oncology CTN is responsible for, but also to facilitate the development of other tools to educate, evaluate, and foster professional growth. These tools could be developed by any facility or organization that employs or has oncology CTN membership. Ways in which the competencies can be utilized include but are not limited to:

- Writing job descriptions for oncology CTNs
- Developing orientation programs for novice oncology CTNs
- Developing continuing education curricula and other resources applicable to novice and experienced oncology CTNs
- Providing guidance to experienced oncology CTNs who are preceptors of new oncology CTNs
- Developing competency checklists to delineate performance expectations for novice oncology CTNs
- Creating tools for CTN self-evaluation as well as documentation of progress by preceptors and management
- Providing the basis for the development of an oncology CTN certification
- Promoting and educating others about the role of oncology CTNs in an organized format.

Nationwide, recruitment and retention of CTNs (clinical research coordinators) is poor, with the majority of coordinators having less than three years of experience in the role (Neuer, 2002). One model of predicting turnover indicated a relationship between promotion opportunities, autonomy, personal accomplishment, and work experiences with coordinators leaving their jobs. The authors suggested employee development programs as one intervention to decrease turnover (Granda, Duane, Munz, & Cannon, 2009). Oncology CTNs usually are experienced in the care of patients with cancer and then gain knowledge about responsible research conduct informally from investigators or other qualified research professionals and administrators. A review from a large oncology institute seeking to improve the education of their novice CTNs found an increase in the confidence level of their new oncology CTNs after the implementation of a competency checklist in addition to a formal education plan (Francis et al., 2008). The use of established competency statements to guide the education of novice oncology CTNs can improve job satisfaction, autonomy, retention, and ultimately the conduct of good research and improvement of patient care.
Initial Requirements

CTNs are pivotal to the conduct and outcomes of a clinical research study. To accomplish this, CTNs are expected to bring several inherent skills that will improve their ability to be successful in their role (Reese, 2009). These skills include:

- Strong verbal and written communication skills
- Strong interpersonal skills
- Ability to work in teams
- Ability to work autonomously
- Ability to problem solve
- Strong organizational skills and attention to detail
- Ability to set priorities and reprioritize quickly
- Comfortable with change and new situations
- Ability to learn quickly
- Ability to utilize computers and basic computer programs.

To supplement these skills, the following professional experience and education are recommended:

- Oncology nursing experience, or a basic oncology course for those without previous oncology clinical experience
- ONS Chemotherapy and Biotherapy Course or equivalent course (if working on trials related to antineoplastic therapy and do not have previous chemotherapy administration experience/education)
- ONS Shedding Light on Clinical Research: An Introduction to Clinical Trials Nursing webcourse or equivalent clinical trials education program
- Human subjects protection training
- Drug dose calculation training or experience

Summary

The transition into the CTN role is not a simple one. Nurses must adjust their mindset from a focus on a patient’s cancer experience to one of how that experience, on the aggregate, affects the outcome of a protocol and the future of a potential therapy for the disease involved (Ermete, 2008). However, because of the complexity of cancer and the demands it places on patients, a balance also must be learned and past nursing skills expanded upon. A better understanding of the evolving role and responsibilities of CTNs can be instrumental in promoting the contributions and legitimacy of nursing to the successful conduct of clinical research (Deininger, 2008). The goal is to help prepare novice oncology CTNs to carry out not only their role in a competent and standardized manner but also their position within the global, interdependent clinical research enterprise (Klimaszewski, Bacon, Deininger, Ford, & Westendorp, 2008b).

References


Oncology Clinical Trials Nurse Competencies

The oncology clinical trials nurse demonstrates critical thinking and implementation of the nursing process, thus providing leadership in the conduct of clinical trials, improving outcomes for patients, and enhancing study integrity. This is accomplished through competent practice in the following functional areas.

I. PROTOCOL COMPLIANCE

The oncology clinical trials nurse facilitates compliance with the requirements of the research protocol and good clinical research practice while remaining cognizant of the needs of diverse patient populations.

A. Identifies the requirements of various types and phases of clinical trials, including objectives, sample sizes, and patient care needs.

B. Identifies sources for and facilitates adherence to current regulations, guidance, and policies that affect research at the institutional, state, federal, and international levels.

C. Promotes compliance with the varied processes and procedures required by different types of sponsors (e.g., private industry, National Cancer Institute Cancer Therapy Evaluation Program, investigator-initiated).

D. Protects patient, protocol, and scientific confidentiality by ensuring security of research data and personal health information.

E. Participates in discussions regarding feasibility of protocol implementation based on knowledge of institutional capabilities and limitations, therapy, or population of interest.

F. Complies with the International Air Transport Association and institutional policies for shipping and receiving biological specimens, experimental agents, and devices.

G. Collaborates with the research team to implement procedures for maintaining patient study participation from enrollment through completion.

H. Identifies the institutional review board (IRB) of record (local, central, or commercial), protocol-related policies of the IRB, and preferred contact method.

I. Participates in providing timely, informative, and accurate communication to the IRB as required.

J. Facilitates and participates in the preparation for and implementation of scheduled and unscheduled meetings with external and internal monitors and auditors, including but not limited to the U.S. Food and Drug Administration (FDA), Medicare reviewers, the IRB, and quality assurance.

K. Ensures validity of research results by ensuring timely, accurate, and complete data documentation, reporting deviations, violations, and serious adverse events.

L. Collaborates with principal investigator, pharmacy, and other appropriate personnel to ensure proper use of and accountability for experimental devices or drugs as indicated.

II. CLINICAL TRIALS-RELATED COMMUNICATION

The oncology clinical trials nurse utilizes multiple communication methods to facilitate the effective conduct of clinical trials.

A. Ensures ongoing formal and informal communication regarding clinical trials with team members.

B. Provides general clinical research as well as trial-specific information to research, clinical, and other organizational staff.

C. Develops relationships with referring physicians, clinical staff, and ancillary departments to facilitate compliance with and accrual to clinical trials.
D. Participates in study initiation meetings.
E. Provides education related to clinical trials to patients and their significant others.
F. Advocates for clinical trials by participating in community outreach efforts to provide general clinical trials education when opportunities arise.
G. Advocates for the safety and care of clinical trial patients as well as for the promotion and integrity of the clinical trial.

III. INFORMED CONSENT PROCESS

The oncology clinical trials nurse demonstrates leadership in ensuring patient comprehension and safety during initial and ongoing clinical trial informed consent discussions.
A. Ensures the initial and ongoing consent process is performed and documented in compliance with FDA, International Conference on Harmonization Good Clinical Practice (GCP), institutional, sponsor, IRB, and other applicable regulations, guidances, and policies.
B. Participates in the education of clinical trial patients about their clinical trial and significant new information that is forthcoming during or after the conduct of the trial.
C. Assesses for barriers to effective informed consent discussions and implements plans to overcome them.

IV. MANAGEMENT OF CLINICAL TRIAL PATIENTS

The oncology clinical trials nurse uses a variety of resources and strategies to manage the care of patients participating in clinical trials, ensuring compliance with protocol procedures, assessments, and reporting requirements as well as management of symptoms.
A. Collaborates with the investigator to ascertain study patient eligibility for a clinical trial, including documentation of criteria specified in the protocol.
B. Ensures adherence to the protocol schedule of events and other requirements.
C. Ensures scheduling of all procedures required to assess for adverse events and disease response to the study intervention.
D. Ensures the successful completion of correlative components of the clinical trial (e.g., pharmacokinetic, pharmacoeconomic, and quality-of-life studies).
E. Assesses patients for trial-related and non–trial-related symptoms and ensures evidence-based symptom management while maintaining trial compliance.
F. In collaboration with the investigator, assesses patients for adverse events and then documents and reports these findings per the protocol and FDA, sponsor, and IRB policies.
G. Utilizes adverse event assessment data and clinical judgment to determine if a dose-limiting toxicity has occurred or if any treatment schedule or drug dose modifications are necessary and communicates findings to the study team and sponsors.
H. During phase I/dose escalation studies, collaborates with the principal investigator to determine when the maximum tolerated dose has been achieved based on adverse event assessment data and clinical judgment.
I. Evaluates disease response results and physical assessment data in conjunction with the principal investigator to determine response per the protocol.
J. Supports and evaluates patient adherence to the protocol by utilizing various methods to assist with documentation, patient education, and study agent return.
K. Identifies vulnerable patients who require increased nursing assessment and management in addition to the clinical trial requirements.

V. DOCUMENTATION

The oncology clinical trials nurse provides leadership to the research team in ensuring collection of source data and completion of documentation that validate the integrity of the conduct of the clinical trial.

A. Complies with regulations, institutional policies, and sponsor requirements governing source data and documentation.

B. Documents assessment, management, and evaluation in source documents for patients on clinical trials as appropriate to the protocol and role.

C. Educates research and clinical team members regarding appropriate and accurate source documentation for participants in clinical trials.

D. Ensures that relevant data from the source document are abstracted and recorded in the clinical trial case report forms and that every data point can be verified within the source document.

E. Follows appropriate guidelines in making corrections to data entry in clinical records and case report forms as recommended by good clinical practices, standards, or institutional procedures.

F. Ensures that all regulatory documents are processed and maintained per institution, IRB, and GCP regulations.

G. Demonstrates proficiency in the use of clinical and research-related computer programs.

VI. PATIENT RECRUITMENT

The oncology clinical trials nurse utilizes a variety of strategies to enhance recruitment while being mindful of the needs of diverse patient populations.

A. Assists in implementation of recruitment plans to identify and assess individuals who might be eligible for clinical trials, taking into consideration the study entry criteria, required procedures, and other potential factors.

B. Identifies and develops processes to overcome barriers to recruitment related to patient demographic factors, underserved populations, and healthcare system influences.

C. Identifies institutional or community-based resources or groups that can assist in achieving recruitment goals.

VII. ETHICAL ISSUES

The oncology clinical trials nurse demonstrates leadership in ensuring adherence to ethical practices during the conduct of clinical trials in order to protect the rights and well-being of patients and the collection of quality data.

A. Advocates for ethical care of clinical trial patients and the conduct of clinical trials in accordance with standards of nursing practice.

B. Promotes ongoing compliance with key ethical concepts by the research team, including informed consent, documentation, respect for persons, beneficence, and justice.

C. Ensures that members of vulnerable populations enrolled in clinical trials are identified and that their rights are addressed.

D. Identifies and follows institutional procedures to report any falsification of data or scientific misconduct.
VIII. FINANCIAL IMPLICATIONS

The oncology clinical trials nurse identifies the financial variables that affect research and supports good financial stewardship in clinical trials.

A. Describes the key components included in study budgets and institutional resources for budget details.

B. Confers with the principal investigator or finance personnel when protocol revisions will affect the costs of protocol management.

C. Identifies routine care versus research-related costs, the financial impact on patients, and any need for financial counseling.

D. Ensures and tracks submission of specified items (e.g., completed case report forms, specimens) to facilitate timely recovery of protocol-related activity costs.

E. Ensures that stipends to patients for protocol-related activities are disclosed to the IRB during approval of the consent form.

IX. PROFESSIONAL DEVELOPMENT

The oncology clinical trials nurse takes responsibility for identifying his or her ongoing professional development needs and seeks resources and opportunities to meet those needs, such as through membership in nursing, oncology, or research organizations.

A. Participates in educational opportunities to increase knowledge about clinical trials, regulations and guidance, and the role of the CTN.

B. Seeks resources on an ongoing basis that provide oncology treatment and nursing practice updates, such as through professional mentoring and meetings, journals, and Web sites.
Appendix A. Glossary

Clinical trials nursing utilizes a unique language relative to the trial process. Understanding the common terms is part of the assimilation of knowledge required to function in the clinical trials nurse role. Some of the core knowledge definitions and terminology used in the trial process include the following.

- **Clinical research**: A scientifically rigorous process to answer questions and provide ongoing knowledge that is evidence based.
- **Data**: Information collected in the clinical trial used to support a final conclusion regarding the question posed in the trial. Data must be supported by source documents, and scientific integrity must be maintained through data reliability.
- **Phase**: A term used to indicate the stages of development from the first step of human testing to presentation for approval. Phases are designed to answer specific questions related to side effects, dosage, efficacy, and equivalency to approved products. Phases typically include phase I, phase II, phase III, and possibly phase IV.
- **Protocol**: Working document specific to an individual clinical trial that outlines the stage, type of trial, and intervention to be used in the research. It includes the objectives of the trial, the interventions and data required to address study objectives, known preclinical and clinical background for the interventions, inclusion/exclusion requirements to participate in the trial, and steps to conduct the trial.

This glossary is not meant to be inclusive. It provides a limited listing of terms to increase the clarity of the document. For a more comprehensive listing of research-related terms, go to www.clinicaltrials.gov.