The Dissertation Committee for Sheryl Guiney Forbes Certifies that this is the approved version of the following dissertation:

Implementing an Undefined Job:
A Classical Grounded Theory Study
Exploring the Perceptions of Oncology Clinical Trial Nurses Encountering Ethical Challenges in Practice

Committee:

Carolyn A. Phillips, PhD, RN, Supervisor

Alice S. Hill, PhD, RN, FAAN

Thomas B. Mendez, PhD, RN-BC, CNS

Susan Nilsen, PhD, RN, CNM

Pamela J. Haylock, PhD, RN, FAAN

Dean, Graduate School

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Exploring the Perceptions of Oncology Clinical Trial Nurses
Encountering Ethical Challenges in Practice

by

Sheryl Guiney Forbes, MEd, BSN, BS

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Dedication

For Ethan and Isaac.

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The clinical trial nurse (CTN) has been recognized as a specialty nursing practice in which the nurse balances the care of a volunteer research participant with the requirements of a clinical trial; the oncology clinical trial nurse (OCTN) specifically cares for the oncology patient enrolled in a clinical trial. A majority of the research is devoted to the role and obligations of the nurse in this specialty practice. While some nursing research provides examples, real or supposed, of ethical challenges CTNs or OCTNs might encounter in practice, there is little information on how the nurses manage those encounters.

This Classical Grounded Theory (CGT) dissertation explored the ethical challenges experienced by OCTNs in their professional practice. CGT is an inductive methodology to study a social process in which little is known and develop a theory grounded in the data (Glaser, 1998). This CGT study used the procedures of constant

comparative methodology (CCM), coding, memoing, and theoretical sampling (Glaser, 1978, 1998) to analyze interviews from twelve OCTNs.

The analysis of the study data resulted in identifying the participant's main concern and substantive theory, *Implementing an Undefined Job*. OCTNs resolve their main concern by *figuring it out*; they learned from their own experiences and applied this knowledge to future situations in an effort to better understand how to manage an ethical challenge if it occurred again. *Learning as you go*, *utilizing their assets*, *standing their ground*, and *managing hope* emerged as conceptual categories related to the participants' main concern and the core category. A theoretical understanding of the OCTNs' experiences managing ethical challenges fills a gap in the nursing literature and provides a framework for how OCTNs manage and respond to those challenges in their professional practice.

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List of Abbreviations

UTMB	University of Texas Medical Branch
CGT	Classical Grounded Theory
CTN	Clinical Trial Nurse
OCTN	Oncology Clinical Trial Nurse
FDA	Federal Drug Administration
ICH	International Conference on Harmonization
GCP	Good Clinical Practice
IRB	Institutional Review Board
ANA	American Nurses Association
IACRN	International Association of Clinical Research Nurses
ACRP	Association of Clinical Research Professionals
SOCRA	Society of Clinical Research Associates
ONS	Oncology Nursing Society
CCM	Constant Comparative Methodology
RN	Registered Nurse
BSN	Bachelor of Science in Nursing
MSN	Masters of Science in Nursing
OCN	Oncology Certified Nurse
CCRP	Certified Clinical Research Professional
NP	Nurse Practitioner
NE	Nurse Educator

Chapter 1 Introduction

This Classical Grounded Theory (CGT) dissertation explored the ethical challenges experienced by oncology clinical trial nurses (OCTN) in professional practice. Chapter One presents the background of the study, the significance of the study, the research question and the aim of the study. The Chapter also provides an overview of the methodology, research design, and overview of the findings. Chapter One concludes with a plan for the remaining chapters.

BACKGROUND AND SIGNIFICANCE OF THE STUDY

The American Nurses Association (ANA) recognized the Clinical Trial Nurse (CTN) as a specialty practice in 2016. The same year, ANA and the International Association of Clinical Research Nurses (IACRN) (2016) collaborated to publish the *Clinical Research Nursing: Scope and Standards of Clinical Practice* which describes the professional role and obligations of the nurse in this role. Also the same year, the Oncology Nursing Society (ONS) published the Oncology Clinical Trial Nurse (OCTN) Competencies (Oncology Nursing Society, 2016) standardizing the practice for oncology clinical trial nurses by identifying the knowledge and behaviors for novice and experienced OCTNs.

Much of the literature is devoted to examining the role and obligations of the nurse in the specialty practice of clinical trial nurses (CTNs) (ANA & IACRN, 2016; Bevans et al., 2011; Castro et al., 2011; Di Giulio et al., 1996; Mori et al., 2007; Offenhartz et al., 2008; Purdom, Petersen, & Haas, 2017). Authors identify possible ethical dilemmas that may be encountered by CTNs who are managing clinical trials of experimental drugs,

including ethical challenges involving informed consent, protocol compliance and documentation, the management of patients, and recruitment and retention of patients in clinical trials (Barrett, 2002; Cantini & Ells, 2007; Chamorro & Appelbaum, 1988; Cisar & Bell, 1995; Di Giulio et al., 1996; Hubbard, 1982; Kaempfer, 1982; McEvoy, Cannon & MacDermott, 1991; Ocker & Plank, 2000). While some nursing research provides examples of ethical challenges, real or supposed, there is little information on how the CTNs managed those dilemmas. Prior to this study, the perceptions of OCTNs managing ethical challenges in professional practice was not explored using a qualitative method. Furthermore, no extant theories have been identified that address the experiences of OCTNs managing ethical challenges in their specialty practice of nursing.

RESEARCH QUESTION AND AIMS OF STUDY

The research question which guided this study was, "What are the perceptions of the oncology clinical trial nurse (OCTN) regarding the ethical challenges experienced in professional practice?" The aim of the study was to explore the OCTNs' experiences with ethical challenges in practice from the OCTNs' perspective and find out "what is going on" (Glaser, 1998, p. 12) surrounding those challenges. The study also aimed to examine and develop a theoretical framework addressing how OCTNs manage and respond to those challenges.

METHODOLOGY

This research study utilized Glaser's Classical Grounded Theory (CGT) (1978, 1998, 2005, 2011, 2012, 2013, 2014, 2015) to explore the ethical challenges OCTNs experienced in professional practice. CGT is a rigorous, inductive process used to collect,

analyze, and develop theory arising from data about a social process. The CGT researcher sets out to explore how a selected group of participants define their reality through social interactions and resolve their "main concern" (Glaser, 1998, p. 18). CGT examines the data, or concepts, and finds relationships among those concepts (Glaser, 1998). The CGT researcher's goal is to understand "what is going on" (Glaser, 1998, p. 12) and allow the data to reveal patterns of behavior and their relationships, leading to theories which are grounded in the data. CGT is an ideal methodology to use when little is known about a phenomenon (Glaser & Strauss, 1967).

RESEARCH DESIGN

The study proposal was submitted to and approved by the University of Texas Medical Branch (UTMB) Institutional Review Board (IRB). The study used purposive and snowball sampling strategies to recruit Registered Nurses (RNs) who were practicing as oncology clinical trial nurses (OCTNs). A study website was created to provide OCTNs information about participation in the study and to collect data using a typed online synchronous interview. Twelve OCTNs agreed to participate in the study; they had been practicing as full-time or part-time oncology clinical trial nurse for a minimum of two years, able to speak and write in English, had access to a computer, and possessed the computer skills necessary to participate in an online interview. The study data consisted of demographic data, interview data, and the researcher's memos.

Data collection and data analysis are an ongoing, iterative process in a CGT study; they are guided by the synchronous techniques of constant comparative methodology (CCM), coding, memoing, and ultimately, by the emerging theory (Glaser, 1978, 1998). CCM is a strategy used to examine, code, and categorize the collected data. Coding guides

the researcher to conceptualize relationships in the data and allows the theory to emerge from the data. Memoing is used throughout all phases of the study and allows the researcher to keep track of thoughts and ideas about the data and emerging concepts. The goal of data analysis in a CGT study is to produce a substantive theory that described what was going on with the OCTNs when they encountered ethical challenges in professional practice.

OVERVIEW OF FINDINGS

Implementing an Undefined Job was the substantive theory that emerged from the research study. The theory describes how the OCTNs managed ethical challenges in their professional practice. The OCTNs recognized the Clinical Research Nursing Scope and Standards (American Nurses Association and International Association for Clinical Research Nursing, 2016) and the Oncology Nursing Society (ONS) Oncology Clinical Trials Nurse (OCTN) Competencies (Oncology Nursing Society, 2016) as guidelines on how to perform their job, but they believed there was a lack of clear guidance as to the actual implementation of their daily duties.

When the OCTNs were confronted with ethical challenges, they *figured out* how to implement an undefined job by *learning as they went along*, *utilizing their assets*, *standing their ground*, and *managing hope*. The OCTN *figured out* their position by learning from their own experiences and then used that experience to change their practice in an effort to better understand how to manage an ethical challenge in the future. The OCTNs *learned as they went along* by identifying additional resources and learning opportunities to *figure out* how to implement their jobs. The OCTNs *utilized their assets* by realizing they, as the patient's nurse, were sometimes the best asset to provide care or education to the clinical trial patient or by requesting the assistance of other medical professionals to help the

patient. The OCTNs would *stand their ground* if they believed their patient's safety was at risk or there was a risk to the validity of the clinical trial they managed. The OCTN balanced the existence of the patient's cancer diagnosis and the opportunities and challenges offered to the patient with the prospect of treatment on a clinical trial by *managing hope*.

CONCLUSION AND PLAN FOR REMAINING CHAPTERS

Chapter One has introduced the research study and provided an overview of the background and significance of the study, the research question, and aims of the study. The Chapter continued by introducing the methodology, research design of the study, and an overview of the findings.

Chapter Two will provide a review of the current literature. Chapter Three will describe how Classical Grounded Theory (Glaser, 1978, 1998, 2005, 2011, 2012, 2013, 2014, 2015) was applied to answer the following research question: "What are the perceptions of the OCTN regarding the ethical challenges experienced in professional practice?" Chapter Four will provide the study findings and the substantive theory. Chapter Five will provide a discussion of the study findings and substantive theory in relation to the current literature and the implications of the study.

Chapter 2 Review of the Literature

Chapter Two provides a review of current literature for this Classical Grounded Theory (CGT) (Glaser, 1978, 1998, 2005, 2011, 2012, 2013, 2014, 2015) study which explored the ethical challenges of oncology clinical trial nurses (OCTNs) in their professional practice. The Chapter begins with a brief review of oncology, clinical trials, and how ethics is practiced and evaluated in clinical research. The Chapter continues by examining the professional practice of the clinical trial nurse, the guidelines and scope and standards for the practice of clinical trial nurses (CTNs), followed by the Oncology Nursing Society (ONS) Oncology Clinical Trial Nurse (OCTN) Competencies. Ethical issues are then addressed within the clinical trial nurse (CTN) responsibilities of the research informed consent, research protocol compliance, the management of clinical trial patients, and how CTNs participate in patient recruitment and retention. The chapter also addresses the CTNs' ethical responsibilities of moral obligation, beneficence, and non-maleficence.

ONCOLOGY AND CLINICAL TRIALS

Cancer is a group of cells which grow uncontrollably anywhere in the human body. Cancers are divided into types based on where they began developing in the body: carcinomas begin on skin, internal organs or glands; sarcomas begin in the connecting tissue of the body; leukemia is cancer of the blood; and lymphomas are cancer of the lymphatic system. Some cancers can metastasize, or spread, throughout the body and develop new tumors. Cancer diagnoses are unique and the severity of the diagnosis depends on the type of cancer; how much of the cancer is present in the body; whether the cancer,

or possibly cancer metastasis, is considered aggressive; and the length of time before initiating treatment.

Clinical trials are research studies conducted on humans to find new ways to treat a disease or to improve the quality of life for people with a disease. “The goal … is to develop or contribute to generalizable knowledge about human health and illness and to test methods that might improve our ability to prevent, diagnose, and treat illness and provide care for patients” (Grady & Edgerly, 2009, p. 471). Clinical trials of experimental drugs determine the optimal dose of the experimental drug; safety and efficacy; and evaluate side effects of the drugs. A carefully conducted clinical trial is the most reliable method to determine whether an experimental drug is safe and effective to treat certain diseases, such as cancer (National Cancer Institute, 2016).

Oncology clinical trials begin in a laboratory when new drugs are tested in cells and animals. The American Cancer Society (2016) estimates new cancer drugs are studied for at least six years in the laboratory before the drug makes it to a clinical trial with human volunteers. Once the clinical trial begins testing in humans, it can take an additional eight years before the drug is approved by the Federal Drug Administration (FDA) (American Cancer Society, 2016).

Clinical Trial Phases

Experimental drugs must go through various successive phases of clinical trials in order to determine their therapeutic merit and safety. If the drug being tested is successful in one phase, it will proceed to further testing in the next phase. Exploratory testing can begin in humans in Phase 0 in which researchers test drugs to see if the experimental drug reaches the tumor, how the drug works in the human body, and how the cancer cells

respond to the drug. The doses of the experimental medication in Phase 0 trial is very low, so generally volunteers do not experience a clinical benefit from the drug. Not all experimental oncology drugs go through a Phase 0 trial; many oncology experimental drugs begin testing human volunteers at Phase I.

A Phase I trial examines an experimental drug for the first time in a small number of volunteer human patients to establish a safe dose range and identify side effects and/or toxicities. Safety is the main concern for patients during Phase I studies because the side effects in human subjects cannot always be predicted during the previous testing of laboratory studies in cells or animals. A Phase II trial further evaluates safety of the drug in a larger population of participants. In a Phase III trial, the researchers evaluate the experimental drug and compare it to drugs already approved for use to assess the experimental drug's safety and efficacy. Phase III trials often use random assignment of participants either to the experimental drug or placebo (sugar pills) compared to drugs already approved for use by the FDA. Placebos are never used alone in cancer treatment if there is an available treatment which is effective. If a drug is successful in a Phase III trial by indicating a new drug is more effective or safer than the current standard of treatment, the drug is submitted to the FDA for approval. FDA approval allows the drug to move into Phase IV. A Phase IV trial is a wide-spread, post approval process to follow patients after a new drug is approved in order to evaluate the drug over a longer period of time.

Ethical Practice in Clinical Trials

Clinical trials undergo rigorous planning and monitoring to ensure the therapeutic intervention is safe and effective, and risks associated with the intervention's use are reasonable given the potential benefit of the experimental drug. The results of each clinical

trial phase must be judged to be scientifically valid. In addition, volunteer patients must be protected from harm throughout all the clinical trial phases. Each phase of a clinical trial can entail ethical questions and challenges to the patient, medical and nursing staff involved in the patient's care, and the overall conduct of the clinical trial.

Multiple codes of ethics and documents have been created which provide direction and guidance to conducting clinical trials while respecting the rights of the volunteer patient. The Nuremberg Code was written after the Nuremberg Trials at the end of World War II. German physicians were charged with conducting human experiments on concentration camp prisoners without consent. The Nuremberg Code was the first international document concerning experimental trials; it contains the principles for human experimentation and requires voluntary consent of a human subject who is well-informed and fully understands the nature of the experiment (The Nuremberg Code, 2016). The Belmont Report, issued in 1979, identified three core principles for research involving human subjects: respect for persons, beneficence, and justice (The Belmont Report, 2016).

The International Conference on Harmonization (ICH) is the international organization of regulatory specialists in Europe, the United States, and Japan. The ICH outlined guidelines to conduct clinical trials ethically in the guidelines for Good Clinical Practice (GCP) (Good Clinical Practice, 1996). GCP standards define the role and responsibilities of clinical trial sponsors, investigators, and clinical site monitors. GCP standards also include the technical aspects of conducting and monitoring a clinical trial in order to protect the human volunteer and obtain quality data. Four components of GCP review regulations and responsibilities for the sponsor of a clinical trial, the investigator conducting the clinical trial, the Institutional Review Board (IRB) approval and monitoring

of the trial, and the standards for obtaining informed consent (Cassidy & Macfarlane, 1991). The ethical guidelines were created to protect human volunteers as well as to preserve the integrity of the science of experimentation in development in new treatments.

CLINICAL TRIAL NURSE

Nursing involvement in clinical trials is essential to ensure ethical responsibility to the patient. "Nurses, more than any other health professionals, are 'positioned' to promote strategies to assure that data from the trials are complete and meaningful" (Cassidy & Macfarlane, 1991, p. 125). The nurses who manage patients on a clinical trial are part of a specialty practice of nurses who "… continually balance the clinical needs of the participant and the requirements of the research" (American Nurses Association & International Association of Clinical Research Nurses, 2016, p. 1).

Nurses can have an immediate responsibility for a clinical trial and the clinical trial patient by managing a study, recruiting patients for the study, overseeing the informed consent of a patient, managing data, and ensuring regulatory compliance of the trial (Offenhartz, McClary, & Hastings, 2008). Registered nurses who manage clinical trials can have multiple job titles: clinical trial nurse, research nurse, clinical research nurse, clinical trials coordinator, study coordinator, clinical research coordinator, or research nurse coordinator (Bevans et al., 2011; Grady & Edgerly, 2009; Mori, Mullen, & Hill, 2007; Ness, Parreco, Galasi, & O'Mara, 2012; Offenhartz, McClary, & Hastings, 2008). Although the job titles vary from organization to organization, the primary responsibility of the nurse is to manage study patients while safeguarding the integrity of the study. "Nurses specializing in clinical research make important contributions to research integrity, patient care, care coordination and human subject protection; their specialized

knowledge and practice is vital to the clinical research enterprise" (Bevans et al., 2011, p. 7). For the purposes of this study, the term "clinical trial nurse" (CTN) will be used to describe a nurse who manages patients in clinical trials. The term "oncology clinical trial nurse" (OCTN) will be used to describe a nurse who manages patients on oncology clinical trials.

Education for Clinical Trial Nurses

According to American Nurses Association (ANA) and the International Association of Clinical Research Nurses (IACRN) (2016), a baccalaureate degree is usually the minimum educational requirement for a clinical trial nurse (CTN). In the baccalaureate degree program, nurses are introduced to the nursing research process and evidence-based nursing practice. However, there is not specific training to the roles and responsibilities of a nurse who manages clinical trials. CTNs require additional training specific to research and clinical trials. The training is often protocol-specific which can be led by experienced CTNs or research sponsors (ANA & IACRN, 2016).

> It is critical that [CTNs] 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 well-being of study participants, ensuring the data gathered in the pursuit of research are credible and accurate (ANA & IACRN, 2016, p. 33-34).

Many CTNs continue their education through ongoing professional development and specialty practice certification. "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 nursing organizations such as the IACRN" (ANA & IACRN, 2016, p. 34). Certification demonstrates a nurse's mastery of skills and knowledge related to their specialty area. Clinical trial nurses (CTNs) and oncology clinical trial nurses (OCTNs) often have a variety of specialty practice certifications since there is not a certification exclusive to clinical trial nursing. Two research certifications exist for research professionals through the Association of Clinical Research Professionals (ACRP) and the Society of Clinical Research Associates (SOCRA). Both organizations and certifications acknowledge the unique framework surrounding clinical research, but the certifications are not specific to the role of the nurse. Other professionals involved clinical research can obtain these particular certifications as well.

Ambiguity of a Clinical Trial Nurse

Mueller (2001) and Mueller and Mamo (2000, 2002) evaluated the role of the clinical trial nurse (CTN) in semi-structured in-depth interviews conducted between 1992 and 1999. The objective of the interviews was to investigate the dimensions of the professional role of a CTN in various clinical settings. Since there is little formal training for the position of a CTN, many nurses learned about their positions "on the job" (Mueller & Mamo, 2002)

The researchers found the work of a CTN included professional duties in nursing and medicine (Mueller, 2001). "The [CTNs] perform two sets of work simultaneously – they implement medical research protocols, therefore doing the work of clinical medicine, and they institute nurse care measures to patients enrolled in clinical trials, therefore attending to the work domain of nursing" (Mueller & Mamo, 2002, p. 35). Cantini and Ells

(2007) add the CTN's obligation to the sponsor company: "CTNs experience conflict between their loyalty to the investigator, their responsibilities to the sponsoring for-profit companies, and their primary responsibility to serve the interests of the study participants" (p. 128). Overall, there is a lack of role clarity for CTNs when managing clinical trials (Wilkes & Beale, 2005).

CLINICAL TRIAL NURSE GUIDELINES FOR PRACTICE

In 2016, the American Nurses Association (ANA) recognized the specialty practice of clinical trial nurses (IACRN, 2016). "Through specialty practice, the [CTN] makes important contributions to the clinical research process, quality of research outcomes, and most importantly the safe expert care of research participants" (IACRN, 2016). The ANA recognition distinguished the specialized impacts of CTNs in clinical research and the unique needs of patients enrolled in clinical trials. In addition, the ANA also approved a five year acknowledgement of the CTN scope and standards of practice for clinical research nursing.

Scope and Standards of Practice

The ANA and the IACRN (2016) collaborated to publish the *Clinical Research Nursing: Scope and Standards of Clinical Practice.* The partnership was established to approve the specialty practice of CTNs and acknowledge the standards of practice for this specific nursing specialty. "[CTNs] must demonstrate expert clinical skills, show well-developed critical thinking skills, and integrate knowledge of regulatory, ethical, and scientific aspects of clinical research into practice" (ANA & IACRN, 2016, p. 1). CTNs

constantly balance the clinical care of the research patient and the obligations to the research study.

Much of the literature describes the role of the CTN and the domains of this specialty practice (ANA & IACRN, 2016; Bevans et al., 2011; Castro et al., 2011; Di Giulio et al., 1996; Mori et al., 2007; Offenhartz et al., 2008; Purdom, Petersen, & Haas, 2017). ANA and IACRN (2016) observe the domains of the CTN practice which each contain a unique collection of skills and knowledge: human subject protection, care coordination and continuity, contribution to science in general and nursing science/practice, clinical practice, and study management. “It is 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” (ANA & IACRN, 2016, p. 16-17).

ANA and IACRN (2016) state the CTN must be: 1) a clinician by providing direct patient care coordination and data collection related to specific protocol activities; 2) a manager to impact research development and management; 3) an educator in specific CTN education, orientation, or professional development; 4) an advocate for participant advocacy and/or safety; 5) a regulatory specialist to ensure a trial is conducted in accordance with GCP standards; and 6) a nurse scientist to engage in research to improve patient outcomes and healthcare delivery. “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” (ANA & IACRN, 2016, p. 17). CTNs may have involvement in one role or multiple roles depending on their place of employment and the duties assigned to their position.

ANA and IACRN (2016) establish four major principals which guide the CTN's clinical research practice as a combination of GCP guidelines and the fundamentals of nursing. The principals are: 1) safety and self-determination; 2) research informed consent; 3) fidelity to the research protocol; and 4) regulatory compliance. The CTN is required to recognize the research participant as an individual who voluntarily enters into the research. In addition, the clinical trial is expected to be conducted in accordance with international, federal, and state guidelines, and to adhere to the specific protocol approved for the clinical trial.

ANA & IACRN (2016) identify 17 standards for the CTN's role: "The Standards of the [Clinical Trial] Nursing Practice are authoritative statements of the duties that all [CTNs] are expected to perform competently, regardless of role, population, or specialty" (ANA & IACRN, 2016, p. 43). The standards of practice include aspects of care from assessment, planning, and evaluation, to standards of professional performance of communication, education, and resource utilization (ANA & IACRN, 2016). In addition, each standard also has corresponding competencies as evidence of compliance applicable to all levels of nursing including advanced practice nurses.

Oncology Clinical Trial Nurse Competencies

The Oncology Clinical Trial Nurse (OCTN) Competencies, first developed by the Oncology Nursing Society (ONS) in 2010 and later expanded in 2016, were created in a response to the need for a standardization of the professional practice role specifically for oncology nurses. The OCTN concentrates on the coordination and care of patients enrolled in clinical trials in all fields of oncology (Oncology Nursing Society, 2016). "As a licensed

professional nurse, the OCTN brings a background of scientific knowledge, critical-thinking skills, and understanding of individual and group behavior" (ONS, 2016, p. 5).

The OCTN competencies were developed, and later revised, following a three-step process completed by field experts which included a review of literature to revise the previously published competencies, field review, and expert review (ONS, 2016). The competencies were then divided into two levels, Level 1 and Level 2, to identify the knowledge and behaviors necessary to move from the novice to more experienced levels of the role (ONS, 2016). "Behaviors were chosen (instead of skills) because they not only demonstrate the ability to perform a skill but also reflect the OCTN's ability to critically think and determine the most appropriate action in each situation" (ONS, 2016, p. 7). Advancement to Level 2 is primarily determined by at least two years of experience, although this requirement can differ depending on the work environment and an OCTN's involvement in continuing education.

The ONS identifies nine competencies in the OCTN professional role: 1) adherence to ethical standards; 2) protocol compliance; 3) informed consent; 4) patient recruitment and retention; 5) management of clinical trial patients; 6) documentation and document management; 7) data management and information technology; 8) financial stewardship; and 9) leadership and professional development (ONS, 2016).

CLINICAL TRIAL NURSE RESPONSIBILITIES

As delineated in the *Scope and Standards* (ANA & IACRN, 2016), the clinical trial nurse (CTN) has multiple professional responsibilities. Castro et al. (2011) identified five domains of the specialty practice which provide a framework for CTN practice: 1) clinical practice; 2) human subject protection; 3) contributing to the science; 4) care coordination

and continuity; and 5) study management. CTNs work in a wide variety of settings and the specialty practice is a multidimensional role. The CTNs can be found providing direct care for patients in clinical practice, ensuring human subject protection, managing the protocol, and ensuring the patient's needs are met throughout treatment. As indicated by the literature review, the variability in the professional role can lead to possible ethical challenges in practice.

Informed Consent

Both the *Scope and Standards* (ANA & IACRN, 2016) and the ONS Oncology Clinical Trial Nurse (OCTN) Competencies (2016) address the informed consent process. The clinical trial nurse (CTN) must protect volunteer human participants in research by providing comprehensive information to the patient and ensure the patient is able to make an informed and autonomous decision about participating in a clinical trial. The informed consent process must provide complete and accurate information, ensure the patient can comprehend the information and is voluntarily participating in the research, and must avoid therapeutic misconception (ANA & IACRN, 2016); Henderson et al. (2007) explains: "Therapeutic misconception exists when individuals do not understand that the defining purpose of clinical research is to produce generalizable knowledge, regardless of whether the subjects enrolled in the trial may potentially benefit from the intervention under study or other aspects of the clinical trial" (p. e324). The CTN has an important part in the informed consent process by being an advocate for the patient:

> As the patients' advocate, nurses can play a pivotal role at this critical gateway to clinical trials. By explaining to patients how scientific advances are made, describing the patients' role and rights in these studies, and providing sources for

more information, nurses can help patients become more effective partners in the clinical trial decision-making process (Sadler, Lantz, Fullerton, & Dault, 1999, p. 107).

The informed consent process is ongoing throughout a participant's involvement in the research study (ANA & IACRN, 2016). The CTN is responsible for educating the patient about the ongoing trial and any new information about the trial that could affect the patient's participation in the clinical trial. "When nurses inquire about toxicities, administer therapeutic agents, instruct patient regarding management of side effects at home, draw blood, or administer a quality-of-life instrument, they are maintaining and continuing the process of informed consent" (Berry, Doss, Hinds, & Ferell, 1996, p. 509).

The CTN and physician share the effort to educate the patient about the informed consent (Cantini & Ells, 2007; Cisar & Bell, 1995; Hubbard, 1982; McEvoy, Cannon & MacDermott, 1991). However, it often falls on the CTN to answer patient questions during the informed consent process and determine whether the patient understands the clinical trial (McEvoy, Cannon & MacDermott, 1991). The nurse has a unique role in ensuring the patient understands the trial, the risks and alternatives for treatment, and personal benefit (Hubbard, 1982).

The informed consent process is an activity when CTNs should provide patient education. The CTN must verify the informed consent information with the patient and assess the patient's ability to comprehend the information prior to the patient signing the informed consent (Chamorro & Appelbaum, 1988; Cisar & Bell, 1995; Di Giulio et al., 1996; Hubbard, 1982; Kaempfer, 1982; McEvoy, Cannon & MacDermott, 1991; Ocker & Plank, 2000). In addition, Hubbard (1982) believes the CTN can develop educational

materials to help the patient understand procedures, such as diagnostic tests, or potential side effects of the treatment so the patient is able to formulate questions prior to the informed consent process.

Ethical issues can have the potential to arise during the informed consent process. Chamorro and Appelbaum (1988) distinguish multiple factors surrounding the informed consent process and the ethical dilemmas that may develop. The CTN is responsible to protect the patient and must ensure the patient has enough information about the clinical trial to provide informed consent. If the CTN witnesses an informed consent, the nurse must feel comfortable with the patient's understanding and ensure the patient was not pressured to sign the consent. The CTN, therefore, bears legal accountability for providing informational material to the patient during the informed consent process. Often, the CTN must translate the consent to assist with the patient's comprehension. In addition, CTNs run the risk of an ignorant consent when patients waive the right to full disclosure. Ignorant consent is when a competent participant does not want to know certain pieces of information about the study and only confines attention to the most significant procedures and risks of the study (Chamorro & Applelbaum, 1988). "In reality, the burden of assisting the patient in truly understanding the informed consent is likely to fall on the nurse," (Chamorro & Appelbaum, 1988, p. 807).

Protocol Compliance and Documentation

Protocol compliance is a core a principle which guides clinical research: "Research studies are conducted as planned, with strict adherence to the design to reduce or eliminate protocol deviations" (ANA & IACRN, 2016, p. 24). The CTN is ultimately responsible for coordinating the patient's care as well as the research project (McEvoy, Cannon &

MacDermott, 1991). The ONS Oncology Clinical Trial Nurse (OCTN) Competencies also focus on protocol compliance as part of the OCTN's responsibilities (2016). In addition to adhering to federal and state regulations regarding clinical trials, the OCTN must identify the trial objectives and all procedures required by the study sponsor or institution; the OCTN must also provide overall protection of the patient, communicate with the Institutional Review Board (IRB), and ensure the validity of results (ONS, 2016).

An additional OCTN responsibility is to "…provide leadership to the research team to ensure accurate source documentation and maintaining essential documents that validate integrity in the conduct of the clinical trial" (ONS, 2016, p. 16). The clinical trial nurse (CTN) must evaluate the data, appropriately document the information, and make corrections as indicated by Good Clinical Practice (GCP) standards. The CTN is responsible for managing the data so the study's questions can be promptly and competently answered (McEvoy, Cannon & MacDermott, 1991).

Management of Patients

The ONS Oncology Clinical Trial Nurse (OCTN) Competencies (2016) identify the management of patients as the OCTN using "a variety of resources and strategies to manage the care of patients participating in clinical trials, ensuring compliance with the protocol procedures, assessments, and reporting requirements as well as management of symptoms" (p. 14). The OCTN must ensure the patient's eligibility for a clinical trial as well as certifying the patient adheres the protocol's schedule and protocol-required tests and evaluations. Furthermore, the OCTN is expected to evaluate the patient's side effects from treatment and determine if dose modifications are necessary based on the treatment protocol.

The ANA and IACRN (2016) combine the coordination of healthcare delivery and health teaching and the promotion to manage patients' well-being during a clinical trial. The clinical trial nurse (CTN) is responsible to ensure continuity of care by collaborating with other healthcare inter-professional teams. When the CTN documents the patient's response to treatment and collects data, the CTN has an opportunity to anticipate adverse events and develop patient specific nursing care (McEvoy, Cannon & MacDermott, 1991). Di Giulio, et al. (1996) believe the CTN should ensure good communication with professionals of other disciplines to ensure continuity of care for the patient during participation in a clinical trial.

Patient Recruitment and Retention

The ONS Oncology Clinical Trial Nurse (OCTN) Competencies state the OCTN "utilizes a variety of strategies to enhance recruitment and retention while being aware and respectful of the needs of diverse patient populations" (ONS, 2016, p. 13). The OCTN, therefore, has an obligation to develop procedures to overcome obstacles in recruitment such as demographics or underserved groups.

A clinical trial nurse (CTN) has the capacity to increase enrollment in a trial by their professional involvement with the physicians and their patients:

> CTNs can proactively identify candidates for studies, notify physicians of trial availability and required pre-enrollment testing, conduct protocol-related education and the informed consent process, and initiate patient enrollment, thus freeing physicians to devote more time to other responsibilities and ensuring that patient eligibility is evaluated by individuals most familiar with the study protocol (Barrett, 2002, p. 1094).

In addition, CTNs can stimulate strategies to increase enrollment into trials in which they manage such as increasing community awareness about the clinical trial process. “CTNs most valuable contribution to the recruitment process, however, involve providing patients with sufficient information and support to make the best possible decision about participation” (Barrett, 2002, p. 1095).

CLINICAL TRIAL NURSE PRACTICING ETHICALLY

The ANA & IACRN (2016) Standards of Professional Performance Standard 7 says the clinical trial nurse (CTN) is expected to “practice ethically” (p. 63). Standard 7 and the accompanying competencies integrate the American Nursing Association (ANA) Nursing Code of Ethics (2015) as the moral foundation of nursing, and therefore clinical trial nursing. The CTN’s ethical responsibilities include advocating for the rights and safety of research participants, safeguarding confidentiality of the subject’s data and information, professional accountability, and collaboration to assimilate standards of social justice (ANA & IACRN, 2016). The ONS Oncology Clinical Trial Nurse (OCTN) Competencies also address ethical dilemmas as part of the fundamental practice of clinical standards (ONS, 2016). Both the *Scope and Standards* (ANA & IACRN, 2016) and the ONS OCTN Competencies (2016) detail the knowledge and behaviors the clinical trial nurse (CTN) must demonstrate in order to operate morally and justly to protect the rights and well-being of the research participant. The ONS OCTN Competencies state the OCTN must “… promote ongoing compliance with the key ethical concepts of respect for individuals, beneficence, and justice” (ONS, 2016, p. 9).

The clinical trial nurse (CTN) is obligated to protect the patient in a clinical trial, while at the same time, ensuring quality data is collected from the study. Cox and Avis’s

(1996) review of literature revealed it was common for nurses to provide much of the care and support to patients during treatment on clinical trials. However, it was also noted ethical issues could develop surrounding the CTN's respect for autonomy, beliefs of justice, informed consent, disclosure of information about treatment, and patient decisions concerning clinical trial participation. Wilkes and Beale's (2005) qualitative study found there was a lack of role clarity for CTNs who experienced conflict between their obligations to the patient and their obligations to the clinical trial. Oberle and Allen (2006) also found the CTN's role of a patient advocate had the potential to interfere with a clinical trial.

The CTNs' basic principles of ethical standards include the principles of beneficence and non-maleficence. Beneficence is a desire to do good and is considered the core principle of nursing patient advocacy (Beauchamp & Childress, 2009). Non-maleficence is doing no harm to the patient (Beauchamp & Childress, 2009). The CTN who is conducting a clinical trial must feel confident about the investigational treatment of a patient or the CTN could begin to believe the clinical trial is denying patients in treating their disease. The possibilities of ethical dilemmas in balancing beneficence and non-maleficence could place the nurse "… in a morally difficult position when having to make a decision about whether to act on perceptions of patients' best interest or to follow the study protocol" (Oberle & Allen, 2006, p. 183). The CTN may be motivated to make a decision about acting on the patient's best interest or following the clinical trial (Oberle & Allen, 2006).

> "(Nurses) make decisions based upon what the patient wants, what the physician wants, and what they as nurses want. The process of deciding includes trying to be objective and identifying the priorities, using diplomacy and deciding when or

when not to act. In deciding, they want to prevent harm and feel comfortable with the decision" (Gold, Chambers, & Dvorak, 1995, p.140).

GAPS IN THE LITERATURE

The majority of the research surrounding the specialty practice of CTNs has led to examining the professional role. Various researchers have identified possible ethical dilemmas that may be encountered by CTNs who are managing clinical trials of experimental drugs, including ethical challenges involving informed consent, protocol compliance and documentation, the management of patients, patient recruitment, and retention. There is no literature, to date, which has utilized a qualitative approach to address the oncology clinical trial nurse (OCTN) perspective about ethical challenges experienced during the management of clinical trials. Moreover, there are no existing theories addressing the perceptions of the OCTNs managing ethical challenges. This innovative study used Classical Grounded Theory (CGT) (Glaser, 1978, 1998, 2005, 2011, 2012, 2013, 2014, 2015) to explore the following research question: "What are the perceptions of the OCTN regarding the ethical challenges experienced in professional practice?"

SUMMARY OF CHAPTER TWO

Chapter Two provided a review of the literature pertaining to the topic of clinical trial nurses (CTNs), and specifically oncology clinical trial nurses (OCTNs), and ethical challenges in their specialty practice. The Chapter began with a review of oncology, clinical trials, and how ethical practice was evaluated in clinical trials. The Chapter also examined the professional practice of CTNs, the guidelines and the scope and standards of practice for CTNs, and the ONS OCTN Competencies. Ethical issues were discussed

concerning the informed consent, the research protocol compliance, the management of clinical trial patients, patient recruitment, and patient retention. Ethical responsibilities of the CTN concerning moral obligation, beneficence, and non-maleficence were also addressed. Finally, Chapter Two identified the gaps in the literature that support the need for this CGT study exploring the ethical challenges experienced by OCTNs in professional practice.

PLAN FOR REMAINING CHAPTERS

Chapter Three will describe how Classical Grounded Theory (CGT) (Glaser, 1978, 1998, 2005, 2011, 2012, 2013, 2014, 2015) was applied to answer the following research question: "What are the perceptions of the OCTN regarding the ethical challenges experienced in professional practice?" Chapter Four will provide a description of the demographic data, the study findings and the substantive theory. Chapter Five will provide a discussion of the study findings and substantive theory in relation to the current literature, the implications of the study, and the study's strengths and limitations.

Chapter 3 Methodology

Chapter Three describes the design of this study and its use of Classical Grounded Theory (CGT) (Glaser, 1978, 1998, 2005, 2011, 2012, 2013, 2014, 2015) to the following research question, "What are the perceptions of the oncology clinical trial nurse (OCTN) regarding the ethical challenges experienced in professional practice?" The Chapter begins with a description of CGT and it significance for use in this study. The Chapter also provides a description of the study specific website used for data collection, participant recruitment, participant inclusion criteria, data collection, and data analysis procedures. In addition, the Chapter describes trustworthiness to evaluate a qualitative study and how CGT can meet those standards. Finally, the Chapter explains how the study presented minimal risks to the human subject participants and how the participants were protected throughout the study

CLASSICAL GROUNDED THEORY

Classical Grounded Theory (CGT), first described by Glaser and Strauss in 1967, and later expanded by Glaser (1978, 1998, 2005, 2011, 2012, 2013, 2014, 2015) is a rigorous, inductive research approach which systematically collects data about a social process. CGT examines the data, or concepts, and finds relationships between those concepts (Glaser, 1998). A CGT researcher's goal is to understand "what is really going on" (Glaser, 1998, p. 12) in the data and to allow patterns of behavior to reveal concepts and theories which are grounded in the data. CGT is unique in that goes beyond describing an experience or topic; CGT generates a theory to "…explain how the issue is processed, managed, or resolved" (Holton & Walsh, 2017, p. 30).

CGT allows the researcher to explore how a group of people define their reality through social interaction, and resolve their "main concern" (Glaser, 1998, p. 18). Holton and Walsh (2017) describe the main concern as "… the issue or problem that occupies much of the action and attention in the research setting" (p. 88). Once the main concern is identified, the researcher is able to identify the core variable and "… explain how that concern or problem is managed, processed, or resolved" (Holton & Walsh, 2017, p. 88). A researcher must stay open while conducting CGT and not let preconceived notions prevent patterns from the data to emerge (Glaser, 1998). CGT is an ideal methodology to use when little is known about a phenomenon (Glaser & Strauss, 1967).

Currently, there is little research about the ethical challenges faced by oncology clinical trial nurses (OCTN). This study examined ethical challenges experienced by OCTNs in their professional practice. The study facilitated the conceptualization of a theory explaining or describing how OCTNs deal with their ethical concerns.

STUDY SETTING.

The study was approved by the University of Texas Medical Branch (UTMB) Institutional Review Board (IRB) at Galveston, Texas (Appendix A). The recruitment of participants began after IRB approval was obtained. Information about the study for potential participants to review and the actual data collection took place on the study website.

The Study Website

A study website was created to provide OCTNs with more information who were interested in participating in the research study (www.OncologyClinicalTrialNurse.com).

The website was also created in order to conduct the study through an online synchronous interview. The website link contained the study's home page which provided the researcher's contact information (Appendix B). The "purpose" link contained a brief description and the purpose of the study (Appendix C). The "participants" link provided the study inclusion criteria (Appendix D). The "anonymous" link contained information on how to interact with the researcher by creating an anonymous email address or blocking a phone number when contacting the researcher by phone (Appendix E). The "forms" link (Appendix F) provided an additional link to the study consent form (Appendix G) for the participants to review. The "chat" link took the user to a password log-in page so the participant could interact with the researcher in an online synchronous interview (Appendix H). Each participant was given a unique password to log-in to the website before the interview by the researcher in an email to the participant which was only active during the interview. The contents of the interview were removed by the researcher prior to performing a subsequent interview.

RECRUITMENT

The study used purposive and snowball sampling strategies to recruit participants. Purposive sampling occurs when "the participants are selected for the purpose of describing an experience in which they have participated" (Streubert & Carpenter, 2011, p. 28). Clinical trial nurses who worked in the field of oncology were purposely selected for this study. The researcher also used snowball sampling in which participants are asked to identify or encourage other potential participants to participate in the study.

The researcher distributed business cards about the study (Appendix I) to oncology clinical trial nurse (OCTN) peers who might be interested in participating in the study. The

business cards introduced the study, provided the researcher's name, credentials, email and phone contact information, and the study website address. In addition, the researcher contacted other OCTNs who were part of the researcher's professional and social network by email (Appendix J) to share information about the study. The email contained general information about the study, the study website address, and participant inclusion criteria. The researcher asked colleagues to share the business cards, the email, or general study information with any other OCTNs they thought would have been interested in participating in the study.

All of the OCTNs interested in the study contacted the researcher by email and indicated they wanted the researcher to respond by email as well. Although the researcher originally had intended to contact the OCTNs by telephone to answer any questions related to the study and to determine whether the OCTN met the study's inclusion criteria, the researcher responded to each OCTN by email with additional information about the study, explained the online synchronous interview process, and asked the OCTN to provide options he/she was available for the interview (Appendix K). A total of fourteen OCTNs contacted the researcher by email and expressed interest to participate in the study. One OCTN did not respond to a follow up email from the researcher after initially contacting the researcher about the study. Another OCTN responded that after she reviewed the inclusion criteria on the website, she realized she did not qualify to participate in the study because she had only been in the position of an OCTN for one year.

When the OCTN emailed the researcher and expressed interest in participating in the study by providing times he/she was available for an interview, the researcher responded with the agreed upon time and unique password for the online synchronous

interview which was only active during the scheduled interview time (Appendix L). The researcher asked the OCTN to review the informed consent on the study website (Appendix G) prior to the interview and provided a direct link to the study's consent form. The researcher's email (Appendix L) also furnished instructions about how the OCTN could log-in to the password-protected website and provided the unique password which was only active during the scheduled interview time. The researcher encouraged the OCTN to be in a location where there would be minimal interruptions during the online synchronous interview. Twenty-four hours before the interview, the researcher resent the email which contained the unique password to log onto the password-protected website as a reminder about the scheduled interview (Appendix L). One OCTN asked to reschedule her interview due to a personal conflict during the originally scheduled interview time. The researcher rescheduled the interview at a more convenient time for the participant.

Participants in the study were licensed registered nurses (RNs) who were currently practicing as a full-time or part-time oncology clinical trial nurse (OCTN) for a minimum of two years. All the participants were able to speak and write in English, had access to a computer, and possessed the computer skills necessary to participate in an online interview. There was no exclusion of participants based on age, ethnicity, or gender. There was no compensation for participation in the study. A total of 12 OCTNs volunteered to participate in the research study. The participants included 11 females and one male, hence this summary will use feminine pronouns to refer to the study participants. Further details about the demographics will be discussed in Chapter Four.

DATA COLLECTION

Data collection for the research study used an adaptation of Nilsen's (2013) approach to online synchronous interviews. The online synchronous interviews provided an additional level of privacy for the participants, allowed the researcher to engage participants from a broader geographic area, and to schedule data collection sessions at the participant's convenience (Nilsen, 2013). Bampton and Cowton (2002) noted online interviews offer a level of anonymity by allowing study participants to use an assumed name, which could increase self-disclosure. Although none of the participants used an assumed name, seven of the 12 participants requested the researcher contact them using their personal email address instead of a work-related email address. The remaining five participants contacted the researcher using a work-related email address. The online synchronous interviews resulted in an immediate intact interview transcript.

Data collection began when the OCTN and the researcher logged onto the password- protected website at the agreed upon interview time. The researcher began the conversation by typing "hello" and waited for the OCTN to respond. When the OCTN responded to let the researcher know she was online, the researcher thanked the OCTN for participating in the study. The researcher used this time to confirm that the OCTN met the study's inclusion criteria. The researcher asked the OCTN if she had had a chance to review the informed consent document and described how the interview would produce a transcript from the time of log-in to the time of log-out. The researcher explained the OCTN could withdraw from the study at any time and the typed conversation would be deleted. The researcher also communicated to the OCTN she had the right to refuse to answer any question asked during the interview. The researcher asked if the OCTN had any questions about participation or the informed consent. Two OCTNs asked the researcher if it was

okay to use specific physician names during the interview. The researcher assured the OCTNs that any information that could be used to identify the participant, her location, other people including physicians, or institutions would be masked or removed, and a de-identified copy of the data would be used for data analysis.

When all questions were answered and the OCTN confirmed that she had read and understood the informed consent, the researcher asked the OCTN to read the "Statement of Consent" at the top of the page (Appendix M) and choose "I agree" or "I do not agree." The researcher encouraged the OCTN to print a copy of the informed consent for her own records. When the OCTN chose "I agree," data collection began.

The researcher asked the OCTN to complete the demographic questions (Appendix N) on the screen then click "submit." The demographic data section included the participant's sex, age, race/ethnicity, education, experience in nursing, experience in clinical trial nursing, experience in oncology clinical trial nursing, information regarding specialty certification, and training specific to the position of clinical trial nursing.

The interview phase of data collection utilized semi-structured questions developed for the research study (Appendix O). The first nine OCTN participants were asked the opening question, "What does the term ethically challenging mean to you?" This question was followed by the researcher asking the OCTN to tell her about an ethically challenging situation she experienced in practice. Based on suggestions made by Dr. Barney Glaser (personal communication, June 2017), the final three participants were asked the opening question, "Tell me what it is like being an oncology clinical trial nurse." The researcher conducted the interview by posting each question into the online synchronous interview and allowing time for the participant to respond. Changing the opening question made no

difference in the unfolding of the participants' response and their experiences in practice. The researcher used probing questions such as "Tell me more about …" and "Describe what you mean when you said …" to encourage ongoing communication about the participant's experiences.

Prior to concluding the interview, the researcher asked the OCTN if there was any further information she wanted to share about her experiences as an OCTN. The researcher thanked the participant for her time and the researcher asked if she could contact the participant with any other questions prior to the study's conclusion. The researcher provided the OCTN with her own contact information and concluded the interview. Each participant was interviewed once by the researcher and no OCTN was contacted for follow up questions. The interviews ranged in length from 74 minutes to 90 minutes and averaged 83 minutes. When the researcher logged out of the online synchronous interview, she changed the password for the website participant log-in so the participant was not able to log into the system again.

DATA MANAGEMENT

The data from the online synchronous interviews was immediately available for download on the researcher's computer from the study's website. The OCTNs' consent to participate and demographic information were available to download as a separate electronic file. The transcript of the online synchronous interview was available to download and any identifying information which could have identified the participant (physician names, place of work, etc.) was removed. Each participant was assigned a code number: the first participant was assigned P1, the second participant was assigned P2, the third participant was assigned P3, and so on. The de-identified transcripts were used for

data analysis. All transcripts and data were saved to the researcher's password-protected computer and backed up on a password-protected portable hard drive stored in a locked cabinet in the researcher's private home office or private work office. All information related to the study on paper or saved electronically will be destroyed at the completion of all study reports.

DATA ANALYSIS

Data analysis in a CGT study is an iterative process that begins with the first set of data and is guided by the synchronous techniques of constant comparative methodology (CCM), coding, memoing, and ultimately, by the emerging theory (Glaser, 1978, 1998, 2011, 2012, 2013, 2014, 2015). Data analysis began immediately after the first interview transcript was downloaded and any participant identifying information was removed or masked.

Constant Comparative Methodology

Constant Comparative Methodology (CCM) is a data analysis strategy used to study, code, and categorize the collected data; CCM is central to the development of a grounded theory (Stern & Porr, 2011). The researcher uses CCM to analyze the data sentence by sentence, line by line; comparing data items to each other, grouping them into themes and categories for the purposes of generating a conceptual theory (Glaser, 1978). CCM results in the creation of significantly richer categories and relationships (Glaser, 1998). CCM is utilized throughout all phases of a CGT study including data collection, data analysis, and theory writing.

Coding

Coding is an essential process of CGT and goes hand-in-hand with CCM; it guides the researcher to conceptualize relationships in the data. “Coding gets the analyst off the empirical level by fracturing the data, then conceptually grouping it into codes that then become the theory which explains what is happening in the data” (Glaser, 1978, p. 55).

Glaser identifies two types of coding: *substantive coding* and *theoretical coding*. *Substantive coding* identifies hidden patterns in the data and indicates the underlying meaning of the pattern (Glaser, 1978). *Substantive coding* begins with *open coding*, which allows the investigator to break up the data into sections and label those sections as conceptual categories (Stern & Porr, 2011). *Open coding* allows the researcher to ask, “What is actually happening in the data?” (Glaser, 1978, p. 57). The researcher identifies and codes the data into as many categories as possible. *Open coding* continues until the researcher identifies the main concern (core variable) of the participants (Stern & Porr, 2011).

Selective coding begins when the core variable has emerged from the data. *Selective coding* means that the researcher begins coding data as it relates to the core variable. *Selective coding* allows the researcher to distinguish patterns among the categories and how the categories relate to one another. *Selective coding* allows the theory to emerge from the data (Stern & Porr, 2011). During *selective coding*, the researcher also begins *theoretically sampling* the data, in which the categories in the emerging theory guide the researcher regarding “where to go next” (Glaser, 1978, p. 37) when collecting data. “[*Theoretical sampling*] is the ‘where next’ in collecting data, the ‘for what’ according to the codes, and the ‘why’ from the analysis in memos” (Glaser, 1998, p. 157). *Theoretical*

sampling generates data leading to saturation of categories and prevents excessive data collection and continual collection of the same data.

Theoretical coding is the process of conceptualizing the relationships among the core category and the substantive codes in theory development (Glaser, 1998, 2005). *Theoretical coding* allows the researcher to "transcend the empirical nature of the data" (Glaser, 1978, p. 55) and integrate the patterns into theory.

Memoing

Memoing occurs during all phases of CGT and is a fundamental process of the methodology. Memos permit the researcher to keep track of thoughts and ideas about the data, concepts, and emerging theory by a free-style process of note-making throughout a study. "Memos are theoretical notes about the data and the conceptual connections between categories" (Holton & Walsh, 2017, p. 36). A researcher writes memos of "… ideas about codes and their relationships as they strike the analyst while coding" (Glaser, 1978, p. 83). Memos are highly sortable, advancing the data to a conceptual level by allowing the researcher to formulate relationships among categories in order to establish a theory (Glaser, 1978).

DATA ANALYSIS PROCESS

The data analysis process for this study followed the procedures set forth by the CGT method with the iterative process of the constant comparative methodology (CCM), coding, and memoing. The application of these techniques led to the emergence of the participants' main concern and the substantive theory, *Implementing an Undefined Job*.

The researcher initiated data analysis using *open coding* and CCM, analyzing the data sentence by sentence, line by line, grouping the data into themes and categories, and identifying as many categories as possible. The goal was to discover "what is really going on" (Glaser, 1998, p. 12) in the data. The researcher also began to memo ideas and questions related to the data. The researcher then interviewed the second OCTN, continuing to analyze the data using CCM and comparing the categories and codes to those identified in the data from the first interview. "The purpose of constant comparison is to see if the data support and continue to support emerging concepts" (Holton & Walsh, 2017, p. 78). The researcher repeated this process with each interview while memoing the data in order to conceptualize theoretical ideas.

The CGT process resulted in the researcher identifying multiple categories in which the oncology clinical trial nurse (OCTN) was *figuring out* how to implement her position. *Figuring it out* was a method the OCTN used in order to protect the patient from risks posed by real or potential ethical issues. Further *open coding* resulted in additional conceptual clusters including: 1) learning how to navigate the job on the job; 2) lack of clarity for the OCTN role boundaries; 3) OCTN competing loyalties with the patient or the protocol; 4) the OCTN going back to knowledge taught in nursing school; 5) redirection to physician; and 6) the OCTN standing her ground with the physician.

The researcher continued to analyze the data using the constant comparison method and memoing. A personal communication with Dr. Barney Glaser (June, 2017) allowed the labeling of the participants' main concern to be clarified to *implementing an undefined job*. "The main concern is a latent pattern that [the participants] simply act on without consciously identifying" (Holton & Walsh, 2017, p. 77). Once the main concern was

identified, the researcher moved into *selectively coding* the data to examine patterns in the categories to determine how the patterns related to one another. After the ninth interview, the researcher was able to *selectively code* and discovered the OCTNs resolved their main concern of *implementing an undefined job* by *figuring it out*, a concept evident from the first participant's interview; *figuring it out* was identified as the core category. "The core category is that pattern of behavior which is most related to all other categories and their properties in the theory which explain how the participants resolve their main concern" (Glaser, 1998, p. 117). The researcher continued to sample and analyze data to confirm four major clusters of conceptual concepts: 1) doing what you know; 2) learning as you go; 3) standing your ground; and 4) passing the buck.

The researcher conducted three more interviews to test the main concern, *Implementing an Undefined Job*, and the core category, *figuring it out*. The additional data confirmed and enhanced the participants' main concern. "When further data yield no new concepts or additional elaboration of their properties or dimensions, *theoretical saturation* has been achieved" (Holton & Walsh, 2017, p. 35). *Theoretical saturation* was reached at the twelfth participant interview.

The substantive theory emerged which focused on the OCTN's main concern, *Implementing an Undefined Job*. The OCTNs resolved their main concern by *figuring it out*, using the processes of *learning as they go, utilizing their assets, standing their ground*, and *managing hope*. The theory will be discussed in detail in Chapter Four.

TRUSTWORTHINESS

Trustworthiness is a term often used to refer to the credibility or plausibility of a qualitative study (Streubert & Carpenter, 2011). Glaser (1978, 1998) established four

criteria to assess the trustworthiness of a CGT study; these include: 1) fit, 2) work, 3) relevance, and 4) modifiability.

Fit: Glaser (1978, 1998) describes fit as how the theory corresponds to the data. Fit means the categories and theory are not forced or selected to match predetermined ideas, concepts, or problems but arise from the data. The findings of this study "fit" because they arose from the data itself and were not preconceived by the researcher. The substantive theory, *Implementing an Undefined Job*, emerged from patterns in the data.

Work: Work is the capacity of the theory "to explain what happened, predict what will happen and interpret what is happening in an area of substantive or formal inquiry" (Glaser, 1978, p. 4). Work implies the practical value and applicability of the theory. The theory, *Implementing an Undefined Job*, emerged from the data and explained patterns of the OCTNs' behavior which could predict and interpret how they managed ethical challenges in their professional practice.

Relevance: Relevance reflects the main concern of the study participants, identified through data collection and analysis (Glaser, 1978, 1998). Glaser (1998) states relevance conjures an "instant grab" to the importance of the study (p. 18). The theory that emerged from the study data clearly reflects the OCTNs participants' main concern, *Implementing an Undefined Job*, and the various processes they use in order to resolve their main concern.

Modifiability: Glaser (1978, 1998) notes that since theory shifts constantly as new information or data emerge; a theory must be able to be modified as new data emerges. *Implementing an Undefined Job* is modifiable because it has the potential to be used in other ethical situations as new data could emerge. Furthermore, the concepts have the potential to be used in a variety of other settings, clinical or non-clinical.

HUMAN SUBJECTS

The study was in compliance with the approved standards set forth by the University of Texas Medical Branch (UTMB) Institutional Review Board (IRB) and presented minimal risk to participants.

The research addressed ethical situations which could have included sensitive personal and private experiences of the participants as well as sensitive information about institutions or other people. The primary risk for participants in this study was loss of confidentiality. The participants were provided with instructions on how to contact the researcher on the study website by creating an anonymous email address or blocking a phone number if the participant contacted the researcher by phone. The participants were encouraged to schedule the online synchronous interview in a private location with minimal interruptions. The researcher conducted the interviews in her private office at home or at her office behind a closed door with a sign indicating she was not available and could not be interrupted. The researcher discussed the risks related to loss of confidentiality with the OCTN participants during the informed consent process. Each participant was assigned a code number and any information that could have been used to identify the participant, her location, other people, or institutions was masked or removed from the data used for data analysis. All research materials including transcripts, computer files, memos, etc. were stored to the researcher's password-protected computer and backed up on a password-protected portable hard drive stored in a locked cabinet in the researcher's home.

The study also presented a risk of being emotionally upsetting to the participants. The purpose of this study was to enhance the understanding of ethical situations encountered by oncology clinical trial nurses, so discussing such situations could have

elicited strong feelings or could have been emotionally upsetting. The researcher did not perceive that any of the conversations during the online synchronous interview were uncomfortable or emotionally upsetting to the participants as the OCTNs spoke freely about their experiences and did not ask for the data collection to be suspended at any time.

SUMMARY

Chapter Three has illustrated the use of the Classical Grounded Theory (CGT) methodology (Glaser, 1978, 1998, 2005, 2011, 2012, 2013, 2014, 2015) and to answer the following research question, "What are the perceptions of the OCTN regarding the ethical challenges experienced in professional practice?" The Chapter has described the study-specific website used for data collection and recruitment, the data collection and data analysis process. The Chapter also demonstrated the criteria used to assess rigor of the scientific study and the protection of the human subjects.

PLAN FOR REMAINING CHAPTERS

Chapter Four will provide a detailed description of this Classical Grounded Theory (CGT) (Glaser, 1978, 1998, 2005, 2011, 2012, 2013, 2014, 2015) study that examined how oncology clinical trial nurses managed ethical challenges. The Chapter will provide a description of the demographic data, the study findings and the substantive theory, *Implementing an Undefined Job.* Chapter Five will provide a discussion of the study findings and substantive theory in relation to the current literature, the implications of the study, and the study's strengths and limitations.

Chapter 4 Results

Chapter Four provides a discussion of the findings from this Classical Grounded Theory (CGT) (Glaser, 1978, 1998, 2005, 2011, 2012, 2013, 2014, 2015) study which explored the research question, "What are the perceptions of the OCTN regarding the ethical challenges experienced in professional practice?" The Chapter begins with a discussion of the study participant demographics. The Chapter then describes the study's findings of the participants' main concern, *Implementing an Undefined Job*, and the substantive theory which emerged from the data.

STUDY PARTICIPANT DEMOGRAPHICS

A total of 12 oncology clinical trial nurses (OCTNs) participated in this research study. Table 4.1 summarizes the demographic data. The participants included 11 females and one male, hence this summary will use feminine pronouns to refer to the study participants. The OCTNs ranged in age from 26 to 60 with an average age of 42. Seven of the OCTNs identified themselves as White/non-Hispanic, two identified as Black, two as Hispanic, and one as Asian/Pacific Islander.

Table 4.1: OCTN Demographic Data (N = 12)

Variable	N
Gender	
Female	11
Male	1
Age	
26 – 36	5
38-48	4
52-60	3
Race / Ethnicity	
White / Non-Hispanic	7
Black	2
Hispanic	2
Asian / Pacific Islander	1

Table 4.2 summarizes the nursing demographic data. Four of the OCTNs had graduated with a Masters of Nursing (MSN), five had a Bachelor's degree in nursing (BSN), and three had a nursing diploma. The OCTNs had been in nursing practice from 4 to 43 years with an average of 12.9 years. The OCTNs had been working as a clinical trial nurse (CTN) from 2 to 30 years with an average of 5.7 years. The participants had been working specifically as an OCTN from 2 to 16 years with an average of 4.5 years. Nine of the 12 OCTNs held nursing certifications. One OCTN held two nursing certifications. Five participants held the certification of Oncology Certified Nurse (OCN), three held the Certified Clinical Research Professional (CCRP) certification, two were Nurse Practitioners (NP), and one OCTN was a certified Nurse Educator (NE).

Table 4.2: OCTN Nursing Experience Demographic Data (N = 12)

Variable	N
Highest Degree of Nursing	
Diploma	3
Bachelors	5
Masters	4
Years as RN	
4 – 7	5
8 – 10	4
22 – 25	2
43	1
Years as CTN	
2 – 3.5	7
4 – 6	4
30	1
Years as OCTN	
2 – 2.5	4
3 – 3.5	3
4 – 6	4
16	1
Certification *	
None	3
OCN	5
CCRP	3
NP	2
Nurse Educator	1

* Total does not add to 12 since some nurses held more than one certification.

The purpose of this Classical Grounded Theory (CGT) (Glaser, 1978, 1998, 2005, 2011, 2012, 2013, 2014, 2015) study was to explore the OCTN's experiences with ethical challenges during the management of clinical trials in professional practice and to explore how the OCTN resolved those conflicts. The research question was: "What are the perceptions of the OCTN regarding the ethical challenges experienced in professional practice?" The data analysis led to the emergence of the main concern of the OCTN, *Implementing an Undefined Job*. The OCTNs resolve (Glaser, 1978) their main concern through the process of *figuring it out*.

IMPLEMENTING AN UNDEFINED JOB

Despite the publication of the *Clinical Research Nursing: Scope and Standards of Clinical Practice* (American Nurses Association and International Association for Clinical Research Nursing, 2016) and the Oncology Nursing Society (ONS) Oncology Clinical Trials Nurse (OCTN) Competencies (Oncology Nursing Society, 2016), the study participants did not believe the boundaries of their position, in actual practice, were clearly defined. The participants did not believe the *Scope and Standards* or the OCTN Competencies addressed exactly how OCTNs were supposed to perform their daily job responsibilities. The OCTNs understood the foundation of their position but they were unsure how to carry out their daily duties finding their role unclear, ambiguous, and vague. The OCTNs described ethical challenges they encountered in their practice as experiences: "… where something did not feel comfortable or right" (P2, L97); "… gut-check scenarios …" (P3, L54); "… no black and white answer …" (P6, L33); "A situation that makes you stop in your tracks …" (P7, 32).

The lack of clarity about the OCTN position caused confusion on the part of other healthcare professionals as well. The OCTNs thought the physicians or principal investigators of the clinical trials did not grasp the full extent of the role of the OCTN: “I think the major struggle . . . is that nobody knows what we do” (P2, L170-171). Another participant said, “There are also a lot of misconceptions out there about what we do” (P11, L172).

The study participants also recognized differences in how other OCTNs manage their position: “It's hard because everyone has their own way of doing things and who knows who is right” (P10, L111-112). For example, the OCTNs’ descriptions of their duties related to the informed consent process for a clinical trial widely varied among the participants. How individual patients were informed about the clinical trial, who provided the information, who answered the patient’s questions, and who obtained the patient’s agreement to participate in the clinical trial varied from institution to institution, department to department, and among the study participants. Some of the OCTNs did not participate in the informed consent process while other OCTNs completed the entire informed consent process with a patient after the physician had introduced the clinical trial and had left the patient’s room. In the latter case, the OCTNs found themselves with the exclusive responsibility to discuss the clinical trial and obtain the patient’s consent to participate in the research study.

In addition, the OCTNs confronted various demands and pressures such as the specific requirements of each protocol, the principal investigators’ viewpoints and expectations of the OCTNs, institutional and departmental policies, trial sponsor obligations and expectations, and unique patient situations such as financial issues, social

issues, or physical issues which could have placed the patient at risk during their participation in a clinical trial. These demands and pressures often competed with one another and created confusing situations which the OCTNs were obliged to navigate. The OCTNs considered these situations as ethically challenging because there was a lack of clear standards they were supposed to follow during the actual day-to-day, patient-to-patient, implementation of their job. The OCTNs' main concern was *Implementing an Undefined Job*.

Figuring It Out

Figuring it out was how the OCTNs resolved their main concern of *Implementing an Undefined Job*: "We just figured things out as we went along" (P11, L155). When *figuring it* out, the OCTNs did what was necessary to protect their patient because the patient's safety always took precedence during treatment on a clinical trial: "I am loyal to my patients first, my department second, and my institution third" (P6, L219-220).

Figuring it out was the process the OCTNs used in order to *Implement an Undefined Job*. When the OCTNs *figured it out*, they learned from their own experiences which resulted in a change in their future practice as an OCTN. For example, one OCTN described what she believed to be an ethically challenging situation with a patient in her clinical trial. The patient's diagnostic examination revealed progression of the patient's disease which required the patient to be removed from the clinical trial; however, the physician treating the patient wanted the patient to continue treatment with the clinical trial's experimental drug. The OCTN explained to this physician that according to the protocol, the patient's treatment with the experimental drug should have been discontinued since there was diagnostic evidence of disease progression. The OCTN reminded this

physician that the principal investigator of the study was the physician responsible for determining disease response and progression while the patient was on trial, not the treating physician. Because of this encounter, the OCTN commented that she learned she had to be thoroughly prepared and changed her practice with this particular physician: “I always come prepared with protocol in hand with this physician now” (P3, L139).

Figuring it out consists of four strategies the OCTNs can take and apply in order to *Implement an Undefined Job*: *learning as you go, utilizing their assets, standing their ground,* and *managing hope.*

Learning As You Go

The study participants described the lack of training for their position: “Our training was on-the-go training” (P2, L138). Each of the study participants received the FDA-required Human Subjects Protection Training and general training on Good Clinical Practice (GCP). In addition, each participant received training which was specific to being an OCTN in a variety of ways through their institutions or departments. Furthermore, most participants described following other OCTNs in their daily activities to learn about their new position. The participants often found this training too short because the other nurses were quite busy managing their own clinical trials during the training: “All the nurses who are asked to help in the training process are so busy themselves, they do not have the time to cultivate an appropriate and successful training experience” (P9, L119-122). As a result, the OCTNs relied on additional colleagues, research team members, principal investigators, and nurse managers for further guidance about their position: “Sometimes I may need to ask another research nurse” (P9, L84-85). “I always have supporting coworkers who are willing to teach me about it” (P11, L135-136). Even though their

colleagues were engaged with their own patients and their own clinical trials, the participants remarked about the tremendous support they received from fellow OCTNs when learning about their new position.

When the OCTNs did not know how to do something, they would "… ask a bazillion questions" (P9, L117) to *figure it out*. The OCTNs located various resources to ensure they were fulfilling their job responsibilities while keeping their patients safe. One OCTN stated she used the research protocol for her clinical trial as her main resource; in addition she sought information from other resources such as books, the internet, and a lecture series to learn more about disease types, departmental and institutional policies at her place of work, and possible alternative treatments. She feared patients would get the impression she did not know what she was doing so she used a variety of resources to gain confidence in her own judgment to make the right decisions and fulfill her responsibilities to the patient as an OCTN.

The OCTNs had to *figure out* how to *Implement an Undefined Job* by finding resources to enhance their knowledge about their position. Overall, the OCTNs believed there was a lack of training for their position and the training they received varied across institutions and departments. The OCTNs found themselves relying on other colleagues, the clinical trial protocol, and various resources such as books, the internet, and policies to help them *figure out* how to *Implement an Undefined Job*.

Utilizing Their Assets

The OCTNs who had difficulty *Implementing an Undefined Job* could also *figure it out* by *utilizing their assets*. Sometimes the OCTNs considered their own skills and knowledge, as the patient's primary nurse, to be the best asset to utilize on behalf of their

patient. At other times, the OCTNs realized the patient's situation called for knowledge and skills outside the boundaries of their nursing practice so they identified other healthcare providers as an additional resource for their patient.

Generally, the OCTNs viewed themselves as the best contact and guide for a patient on a clinical trial: "Nurses are vital to help the patents navigate the studies" (P5, L127-128). "As the clinical trial nurse, I find myself as the go-to for the patient, whether it be protocol related or not" (P6, L153-154). The OCTNs realized they had unique assets as a nurse which could assist their patient throughout the oncology clinical trial process. The OCTNs believed they brought the understanding of a clinical trial to a level the patient could comprehend:

> We can help normalize the process for [the patient], so they don't seem burdened by the research aspect of their care …We add a personalized touch to patient care in the research setting and avoid making them feel like a subject or participant (P12, L190-195).

The OCTNs *utilized their assets* of nursing skills, such as patient assessment, education, and listening, to care for their clinical trial patient. Several participants commented on the importance of patient assessment skills to monitor the patient for side effects from experimental drugs. The OCTNs thoroughly examined their patients for side effects and provided appropriate nursing intervention or requested medical intervention, such as prescribing medications, by other team members with a different license who were able to prescribe medications.

The OCTNs used their skill as a patient educator to inform the patient and encourage dialog about the clinical trial, possible side effects, or the potential outcome of

treatment. One OCTN thought certain physicians did not provide enough detail about the possible side effects from the experimental drugs, so she believed she was obligated to provide further education about possible adverse reactions: “It is important that I talk and explain to the patient, sometimes it takes several sessions of explanations” (P1, L100-101).

The participants remarked about the importance of the OCTNs’ ability to listen to the patient: “You have to be very understanding, open, and empathetic with the patient. Listen and listen some more. Explain. Answer their questions” (P9, L56-58). The OCTNs’ relationships with their patients allowed them to see the patient more holistically; they could see beyond the patient’s cancer diagnosis and the clinical trial to other factors affecting the patient: “The OCTN advocates for the patients, encourages them to advocate for themselves, keeps them informed of all pertinent health information, making sure their wishes are honored” (P7, L139-141). “I know we are all in a hurry, but time is a sacrifice nurses sometimes have to make just so the patients don't feel abandoned and alone” (P9, L64-66).

The OCTNs also *utilized their assets* and realized when they needed to call on the talents and knowledge of other people to assist the patient: “Since I’m usually the point of contact for patients, I try to do what I can to solve their problems or find someone that can help” (P8, L229-230). One OCTN discussed a situation when she was concerned about a patient because the patient had unique personal issues that could affect her participation in the clinical trial:

> The big issue with this patient was that she had extensive hip arthritis to the point where she could barely walk … my concern was that she would fall at home and nobody would know ... I let the social worker know but I don't know if they really

took the time to talk with her. I reached out to some of the other clinical trial nurses and I tried to call organizations and places to see if they had caregivers or something they could get through her insurance or just someone to at least help her (P2, L36-46).

Furthermore, the OCTNs understood the boundaries of the scope of their nursing practice and passed on responsibilities which they did not feel they were competent or qualified to answer. Several OCTNs discussed redirecting questions to the treating physician, especially during the process of obtaining the patient's informed consent to participate in the clinical trial. If the patient asked questions the OCTNs believed were outside of what they could comfortably answer, they *utilized their assets* and directed the medical questions to the physician: "I will get the doctor to answer a question if it relates to whether a drug will cure the patient, or the success rate of a trial" (P1, L66-68). "I'll make the MD come back to discuss things beyond the nuts and bolts of the protocol … I think the physician should at least describe the therapy, how it acts on the disease, at least touch on safety/side effects of the drug, and why they are recommending it" (P3, L202-204, 207-211). "If it's too medical, I'll get the physician back in the room" (P8, L162).

The OCTNs recognized the principal investigator as an asset for helping the patient understand the clinical trial: "When it comes to overall interpretation of the protocol, the principal investigator is ultimately responsible" (P6, L192-193). The OCTNs also found themselves utilizing the physician's knowledge and medical judgement to discuss with the patient the reason a clinical trial was chosen over the standard of care treatment: "I have to have faith that the doctors I work with know what they are doing. They definitely have

more experience with the disease than I do" (P6, L101-103). "Ultimately, it's up to the patient to continue treatment based on the physician recommendations" (P8, L185-186).

When confronted with ethically challenging patient situations, the OCTNs evaluated the issue and *figured out* the best resource to assist the patient. When the OCTNs *utilized their assets*, sometimes they found their own skills to be the best resource while at other times they used their resources as an asset and redirected the patient to someone else who could assist the patient. They *figured it out* by doing what they could with the patient's best interests in mind.

Standing Their Ground

The OCTNs' first obligation is the safety of their patient. If the OCTNs believed the patient's safety was threatened in any way, the OCTNs would *stand their ground* for the best interest of the patient or the clinical trial in which they managed.

The OCTNs would *stand their ground* if they thought the patient was not able to provide informed consent on his or her own behalf. One OCTN explained a situation in which she was asked to obtain informed consent from a patient to participate in a clinical trial. The OCTN went to the patient's room and discovered the patient was waking up from sedation and the patient kept falling asleep while she was talking to him. The OCTN refused to obtain consent from the patient because she believed the patient was incapable of providing informed consent. The OCTN reported:

> I was reprimanded for delaying the patient treatment. The doctor, as well as my supervisor, got onto me and told me that it was not my call to decide whether the patient was capable of signing consent. While not formally punished, I was strongly discouraged from repeating this behavior again. I advised them that I did not feel it

> was appropriate or ethical to consent the patient until sufficient time had passed after the sedation. That is when they told me it was not in my job description to make this determination. I was so offended. I told them that I was a registered nurse and clearly capable of assessing a patient's mental status. Needless to say, they were not happy with me. Either way, I stuck to my guns and refused to consent the patient (P6, L45-63).

Another OCTN refused to draw a blood sample from a comatose hospice patient as requested by a pharmaceutical company. The OCTN *stood her ground* because she was uncomfortable drawing blood during the patient's final hours of life; she also feared taking the blood sample would give the family a false sense of hope for the patient's recovery. One OCTN described how she was pressured by the physicians to enroll patients on her clinical trial and begin protocol therapy as soon as possible. The OCTN *stood her ground* by giving the physician a list of required screening tests and "… painting a realistic picture of the window within which we could start treatment on the clinical trial" (P11, L93-94).

The OCTNs also described their obligation to protect the integrity of the protocols they managed. The OCTNs saw themselves as the gatekeeper for the protocol and would *stand their ground* if they believed the validity of the clinical trial was threatened. Each protocol precisely defined the criteria the patient must have met in order to enroll in that particular clinical trial. Several OCTNs reported instances when physicians attempted to circumvent a protocol's inclusion criteria, so a specific patient could enter that clinical trial. In such instances, the OCTNs found it necessary to reassert the importance of the eligibility criteria to the physician: "This upsets a lot of the doctors, but I think that the eligibility

criteria are meant to be followed not reinterpreted for convenience" (P6, L170-171). "Eligibility criteria is there for protection of the patient and the study data" (P8, L39-40).

Some of the OCTNs found it difficult to *stand their ground* to a physician: "Saying no to a physician, especially forceful ones, is the hardest job for any nurse" (P3, L159-160). Nevertheless, an OCTN who had been involved in clinical research and clinical trials for over ten years explained the importance of training new OCTNs to *stand their ground* with physicians: "… not only are you managing the clinical aspects of patient's care, you have to comply with the protocol. You must empower new nurses to work with physicians and research assistants and speak up when something does not seem right" (P12, L162-164, L171-172).

When the OCTNs were confronted with ethically challenging situations, they would *figure it out* by *standing their ground* for the patient's welfare or if they believed the patient's best interest was threatened. Since the OCTNs saw themselves as gatekeepers for the protocol, they would also *stand their ground* to protect the quality of the data or the integrity of the clinical trial. The OCTNs would *stand their ground* even if it involved some risk to themselves as a nurse because they were convinced what they were doing was the right thing to do for their patient or protocol.

Managing Hope

The OCTNs described ethical challenges they encountered in which there were no true guidelines on how to *manage hope* for the patients in the clinical trial. The study participants had to *figure out* how to *manage hope*: they had to balance the reality of the patient's cancer diagnosis and state of the patient's disease with the possibilities offered by experimental treatment on a clinical trial.

How the OCTNs *managed hope* varied according to each particular patient's situation. *Managing hope* was generally uncomplicated for the OCTNs interacting with oncology patients who were seeking clinical trial treatment for slow growing, non-invasive types of cancers. The patients were able to ask questions and had time to consider whether treatment in a clinical trial was the best option for treatment. In contrast, other OCTNs talked about the difficulty of *managing hope* with patients who were pursuing clinical trial treatment as the last possibility for an option to treat their disease. These patients were eager for a treatment for their disease as they had failed all other treatment opportunities which were available and approved by the Federal Drug Administration (FDA).

Part of *managing hope* for the OCTNs was to ensure they were always honest with their patients, even if the conversations were difficult. For example, one participant stressed the importance of being honest and straightforward with patients about certain clinical trials because some of the side effects of the experimental treatment were not known. One OCTN described an experience with a patient who died because of the side effects of one of the trials she managed. As a result of this experience, she found herself discussing devastating side effects and the prospect of autopsies with other possible clinical trial participants. She stated, "I have learned to be utterly honest about side effects" (P6, 135). Several OCTNs explained the need to be honest about a clinical trial in which an experimental drug would be added to an FDA approved, standard treatment regimen. The OCTNs had to be clear when talking to the patients about the trial that it was unknown whether the addition of the experimental drug would actually enhance the patient's cancer treatment.

At times, the OCTNs found it ethically challenging to be honest and to *manage hope* simultaneously when talking to a patient. One participant described her experiences with patients who called her from different states looking for possible clinical trials for their cancer diagnosis. Although she wanted to find the right words to provide clear and truthful information to share with the patients about available trials at her institution, she also wondered if she was providing false reassurance to the patients: "I always have to find right words and phrases to support the patient and not give them the wrong information" (P4, L47-49).

The OCTNs were aware that some patients enrolled in clinical trials to treat their cancer diagnosis while some patients enrolled with other motivations. The OCTNs stated younger adult patients participated in a clinical trial for a possible cure to their disease. On the other hand, older, elderly, or patients seeking palliative treatment were more likely to participate in a clinical trial to leave a legacy to help other people with their cancer diagnosis. Some of the latter patients also desired extended time with their family members for a special event: "The older patients are more of an altruistic nature. I think they are hoping to buy themselves just a little more time, to make that wedding, see that grandbaby be born, etc." (P6, 265-267).

The OCTNs recognized that participation in a clinical trial places additional burdens on the patient and the patient's family: "Patients make a great sacrifice" (P5, L127). For example, the OCTNs knew their patients often sacrificed additional time or money to travel to a clinical trial site. Frequently the OCTNs found themselves discussing finances related to their treatment: "Patients are always concerned about the expenses, I talk to them about what the clinical trial will pay and what their insurance will pay. Patients

are still concerned about the out of pocket expenses" (P1, L46-48). One participant described a patient for whom *managing hope* involved conversations about the physical and financial burden of participating in a clinical trial:

> There are many patients who cannot physically or financially come and spend enormous amounts of time or money at our institution. The physicians do not understand this at all. I had one patient who slept in the lobby at times because he couldn't afford the hotels. It was so sad. I talked to the doctor and the drug company and received permission for him to receive most of his treatment at home. This allowed him to be able to remain on study and be able to afford to pay his bills (P6, L154-161).

Generally, the OCTNs had positive experiences when they could offer hope with treatment available from a clinical trial: "If I helped at least one patient who is on trial and doing well, I feel accomplished" (P4, L109-110). "I feel like I make a difference in the patient's life and try to make the clinical trial process as easy as possible for them" (P10, L127-128). "It's uplifting to be a part of trials that could be viable as a standard of care treatment" (P7, L163-164). One OCTN described some of the gratification of her position:

> Having the opportunity to provide novel therapies to patients who otherwise have limited to no options is rewarding. I meet patients at a period of their journey when they have, most times, [responded poorly] on standard therapy. It's an opportunity to provide hope in an otherwise disappointing or sad situation (P12, L30-34).

Overall, the OCTNs found *managing hope* to be emotionally exhausting. One participant said it was difficult to uphold the specific inclusion criteria of a clinical trial when the trial appeared to be the final hope of treatment for a patient. Another OCTN

explained a situation in which the treating physician was using different computations of an electrocardiogram reading to meet the protocol's screening criteria so a patient could enroll in a clinical trial. The nurse stated the patient only had days left to live and treatment with the experimental drug was considered a "Hail Mary" (P3, L102), or a final chance, to treat the patient's cancer diagnosis.

The OCTNs *managed hope* so their patients were able to make the best decision about their cancer diagnosis or treatment. The OCTNs had to *figure it out* by understanding each patient's situation, the patient's goals for participating in the clinical trial, and how to best support the patient in that decision. The OCTNs' primary strategy for *managing hope* was to be truthful when talking to the patient. They supported their patients' decision by being honest about treatment side effects and the treatment's potential efficacy; they also supported patients' willingness to make the physical, financial, and time commitment required to participate in the clinical trial. *Managing hope* had an emotional effect on the OCTNs; the experience could be positive if the clinical trial was effective for the patients or if the trial added value to cancer treatment. In contrast, the experience could be emotionally taxing for the OCTNs if the patients were facing a poor outcome with treatment on a clinical trial.

SUBSTANTIVE THEORY: IMPLEMENTING AN UNDEFINED JOB

Implementing an Undefined Job is the substantive theory that emerged from this study which explored the ethical challenges OCTNs experienced in their professional practice. The OCTNs recognized the *Clinical Research Nursing: Scope and Standards of Clinical Practice* (American Nurses Association and International Association for Clinical Research Nursing, 2016) and the Oncology Nursing Society (ONS) Oncology Clinical

Trials Nurse (OCTN) Competencies (Oncology Nursing Society, 2016) as guidelines on how to perform their job. However, the OCTNs did not believe the boundaries and how to perform the daily activities of the position were addressed in these publications. The OCTNs found the obligations of their position ambiguous, unclear, and vague. When the OCTNs were confronted with issues they considered to be ethically challenging, they believed there was a lack of clear standards in the actual implementation of their duties and they had to *figure out* how to handle the situation. The OCTNs' primary focus was their patient's safety; their patient was always the foundation when *Implementing an Undefined Job.* The OCTN figured out how to *Implement an Undefined Job* by *learning as they go, utilizing their assets, standing their ground,* and *managing hope.*

Figuring it out was the process the OCTNs used when encountering what they believed to be an ethical challenge. As the OCTNs learned about their position and how to manage ethical challenges, they *figured it out* as they went along. The OCTNs learned from their own experiences on the job and took that experience to change their practice to better understand how to manage an ethical challenge if it occurred again in the future.

Learning as you go was one method the OCTNs used to *Implement an Undefined Job*. The training for the position of an OCTN varied considerably among institutions and departments. The OCTNs found themselves seeking further resources such as fellow OCTN colleagues, principal investigators, and nurse managers to learn how to implement their job. The OCTNs learned how to *Implement an Undefined Job* from books, the internet, policies, and lecture series to gain knowledge about their job and make the correct decisions when executing the responsibilities of their position.

The OCTNs *figured out* how to *Implement an Undefined Job* by *utilizing their assets*. Many times, the OCTNs believed they were the patient's best asset to provide the best care to the patient as the patient's clinical trial nurse. They believed they were an essential asset to assist the patient throughout the clinical trial process. The OCTNs used themselves as an asset to help the patient navigate the study, to assess the patient with their nursing skills, to educate the patient about the clinical trial or possible side effects of treatment, and to generally listen to the patient's concerns. At other times, the OCTNs *utilized their assets* and requested the assistance of others such as the treating physician, the principal investigator, or other medical professionals to assist the patient. The OCTNs always had the patient's best interest in mind to support the patient's immediate and long-term needs.

The OCTNs would *stand their ground* if they believed the patient's safety was at risk or the validity of the clinical trial they managed was in jeopardy. They would *stand their ground* even if it involved risk to their position because they alleged they were doing the right thing for their patient or protocol. When the OCTNs *stood their ground,* they believed there was a direct danger to their patient's safety. In addition, the OCTNs considered themselves as the gatekeeper for their protocol and *stood their ground* when the reliability or validity of the clinical trial results were threatened. The OCTNs acknowledged *standing their ground* was difficult to do with physicians, but they did so nevertheless so they could protect their patient or protocol.

The OCTNs had to *figure out* how to balance the existence of the patient's cancer diagnosis and the opportunities offered to the patient with the prospect of treatment on a clinical trial by *managing hope*. The OCTNs took each patient's particular situation into

account when *managing hope* for their patient. A major detail of *managing hope* ensured the OCTNs were honest with the patient, even when the conversations were difficult. The OCTNs found the proper words to say to the patients while maintaining truthfulness. The OCTNs recognized there were multiple reasons patients enrolled into a clinical trial and it was important for the OCTNs to communicate their understanding of these reasons to their patients. The OCTNs could have positive or negative experiences of *managing hope* with patients which was sometimes based on the outcome of the patients in their trials.

The substantive theory, *Implementing an Undefined Job*, reflects the OCTNs' determination to do what was best for the patient despite the fact they did not always understand the day-to-day, patient-to-patient, implementation of their job.

SUMMARY

Chapter Four has presented the findings for this Classical Grounded Theory (CGT) (Glaser, 1978, 1998, 2005, 2011, 2012, 2013, 2014, 2015) study that explored the perceptions of the OCTN regarding the ethical challenges they experienced in professional practice. A description of the study participant demographics was followed by a description of the study's findings and a discussion of the substantive theory, *Implementing an Undefined Job*, which emerged from the data.

PLAN FOR REMAINING CHAPTER

Chapter Five will provide a discussion of the study findings and substantive theory in relation to the current literature, the implications of the study, and the study's strengths and limitations.

Chapter 5 Discussion and Conclusions

This research study used Classical Grounded Theory (CGT) (Glaser, 1978, 1998, 2005, 2011, 2012, 2013, 2014, 2015) to explore the ethical challenges experienced by oncology clinical trial nurses (OCTN) in professional practice. Chapter Five will review the research problem and provide a review to the methodology used to answer the research question. Then the chapter will discuss the findings and the substantive theory, *Implementing an Undefined Job*, that emerged from the study findings. Chapter Five will compare the findings to the extant literature and provide implications and the significance of the study. The Chapter will conclude by examining the strengths and limitations of the study, suggestions for future research, and conclusions of the study.

STATEMENT OF THE PROBLEM

In 2016, the role of a clinical trial nurse (CTN) was recognized as a specialty practice by the American Nurses Association (ANA). The *Scope and Standards* describe the professional role and obligations of the nurse in this role (American Nurses Association and International Association for Clinical Research Nursing, 2016). More specifically, the Oncology Nursing Society (ONS) Oncology Clinical Trial Nurse (OCTN) Competencies (Oncology Nursing Society, 2016) standardized the practice for oncology nurses by identifying the knowledge and behaviors for novice and experienced OCTNs.

A review of the literature revealed most of the research is spent examining the role and obligations of the nurse in professional practice. Authors identify possible ethical dilemmas that may be encountered by clinical trial nurses (CTNs) who are managing clinical trials of experimental drugs, including ethical challenges involving informed

consent, protocol compliance and documentation, the management of patients, patient recruitment, and retention. While some nursing research provides examples of ethical challenges, real or supposed, little information is provided on how the CTNs managed those dilemmas. Prior to this study, the perceptions of oncology clinical trial nurses (OCTNs) managing ethical challenges in professional practice was not explored using a qualitative method. Furthermore, there were no extant theories addressing the experiences of the OCTNs managing ethical challenges encountered in practice.

REVIEW OF THE METHODOLOGY

The study utilized Classical Grounded Theory (CGT) (Glaser, 1978, 1998, 2005, 2011, 2012, 2013, 2014, 2015) to examine the ethical challenges OCTNs experienced in their professional practice. The researcher chose CGT because it allowed the researcher to explore "what is really going on" (Glaser, 1998, p. 12) when OCTNs encountered ethical challenges. CGT investigates how a group of people define their reality through social interactions, and resolve their "main concern" (Glaser, 1998, p. 18). The inductive research approach systematically collects data, examines the concepts in the data, and identifies a core category pertaining to the phenomenon of interest, which leads to the emergence of a substantive theory (Glaser, 1998). The researcher used CGT to explore the ethical challenges OCTNs experienced in professional practice to identify the participants' main concern; resulting in the emergence of the substantive theory, *Implementing an Undefined Job*.

Participants for this study were recruited through purposive and snowball sampling strategies. The researcher began recruitment by distributing business cards about the study to OCTN peers and professional contacts. Twelve OCTNs who self-identified as

Registered Nurses (RNs) practicing as OCTNs for a minimum of two years contacted the researcher to participate in the study. The participants were directed to a study website (www.OncologyClinicalTrialNurse.com) created specifically for this research study. The study data was collected within the password-protected website utilizing online synchronous typed interactions which allowed the informed consent process, demographic data collection, and the transcript of the interview available to the researcher in real time.

Data analysis was guided by the synchronous techniques of constant comparative methodology (CCM), coding, and memoing (Glaser, 1978, 1998, 2011, 2012, 2013, 2014, 2015). The data was analyzed line-by-line and CCM was used to code clusters of data into categories which described the participants' "main concern" (Glaser, 1998, p. 18) of *Implementing an Undefined Job*. Additional concepts were identified as related to the main concern which allowed the researcher to *selectively code* and determine patterns in how the relationships were related to one another. The substantive theory, *Implementing an Undefined Job*, emerged from the data by a process of the OCTNs *figuring it out*, which consisted of four strategies OCTNs could take and apply in order to *Implement an Undefined Job*: *learning as you go, utilizing their assets, standing their ground*, and *managing hope*.

FINDINGS: SUBSTANTIVE THEORY "IMPLEMENTING AN UNDEFINED JOB"

Data analysis was used for this Classical Grounded Theory (CGT) methodology (Glaser, 1978, 1998, 2005, 2011, 2012, 2013, 2014, 2015) and led to the identification of the main concern of the participants and the substantive theory, *Implementing an Undefined Job*. The oncology clinical trial nurses (OCTNs) were acquainted with the *Clinical Research Nursing: Scope and Standards of Clinical Practice* (ANA & IACRN, 2016) and

the Oncology Nursing Society (ONS) OCTN Competencies (ONS, 2016) as guidelines on how to perform their job. However, they did not believe either publication addressed how to perform the daily activities of their position. When the OCTNs were confronted with situations which they considered to be ethically challenging, the OCTNs believed there was a lack of standards in how to implement their ambiguous position. With the OCTNs' primary focus of patient safety, they *figured out* how to *Implement Their Undefined Job* when confronted with an ethically challenging situation. The OCTNs learned from their own experiences and applied this knowledge to future situations in an effort to better understand how to manage situations if the ethical challenges occurred again.

The OCTNs used the method of *learning as you go* to utilize research specific training, colleagues, principal investigators, the clinical trial research protocol, or resources such as books, the internet, or lecture series to gain additional knowledge about their professional position. The OCTNs found a lack of training for their position and relying on supplementary resources was their way of *figuring out* how to *Implement an Undefined Job*.

Utilizing their assets was a method the OCTNs applied to ensure they were providing the best care possible for their patients. At times, the OCTNs found their own skills as a nurse as the best asset to assist the patient with navigating the clinical trial, assessing the patient for adverse events from the experimental treatment, providing relevant education to the patient, or to generally listen to the patient's concerns. At other times, the OCTN *figured out* the best resource to assist the patient and *utilized their assets* of the treating physician, principal investigator, or another medical professional when they

were confronted with an ethically challenging situation they believed another professional was better suited to navigate.

Additionally, the OCTNs also *stood their ground* if they felt their patient's safety was threatened or the validity of the clinical trial in which they managed was in jeopardy. The OCTNs *stood their ground* when they believed there was a danger to their patient's safety, even if it involved a risk to their professional position. Furthermore, the OCTNs believed they were the gatekeepers of their research protocol and would *stand their ground* to protect the quality of the data or the integrity of their clinical trial.

In addition, the OCTNs *figured out* how to *manage hope* in an effort to balance the reality of the patient's cancer diagnosis and state of their disease with the prospect of treatment on a clinical trial. *Managing hope* was ensured by the OCTNs' honesty and openness when talking to a patient. The OCTNs supported their patient's decision to participate in the clinical trial while taking into consideration the patient's physical, financial, and time commitments required for participation.

COMPARISON TO THE EXTANT LITERATURE

Prior to the official recognition of the role of the clinical trial nurse (CTN) as a specialty nursing practice by the American Nurses Association (ANA) in 2016, a majority of the literature had examined the role and responsibilities of the CTN position, including duties to the research participant. Discussions of ethical issues experienced by CTNs in the literature cited the guidelines of Good Clinical Practice (GCP) standards or the Institutional Review Board (IRB) as standards CTNs should strive to uphold (ANA & IACRN, 2016). Some of the literature prior to 2016 provides examples of ethical challenges the CTNs might encounter in the management of clinical trials. No literature was identified

specifically examining the perceptions of oncology clinical trial nurses (OCTNs) in regard to ethical challenges experienced in professional practice prior to this present study. Furthermore, no existing theories were identified that address the perceptions of the OCTNs managing their ethical challenges. The following sections discuss how the present study findings compare to the extant literature in the areas of the role of a clinical trial nurse (CTN), the informed consent process, and the demographics and education levels of the participants. In addition, the following sections address how the themes of *figuring it out*, *learning as you go*, *utilizing their assets*, *standing their ground*, and *managing hope* compare to the extant literature.

Role of the Clinical Trial Nurse

The clinical trial nurse (CTN) plays a significant role in the management of clinical trials by balancing the needs of the research participant and the requirements of the research protocol, while ensuring the data in the trial is complete (ANA & IACRN, 2016; Cassidy & Macfarlane, 1991). Recent publications (ANA & IACRN, 2016; Ness & Royce, 2017; Purdom, Petersen, & Haas, 2017) provide further explanation of the roles and responsibilities of the CTN and the oncology clinical trial nurse (OCTN) in practice. The substantive theory, *Implementing an Undefined Job*, expands the literature by identifying the OCTNs still believe the standards and guidelines of their position are ambiguous, unclear, and vague. They believe the daily activities of their position, especially issues surrounding ethical challenges, are not addressed in the publications. *Implementing an Undefined Job* adds depth to the research because it explains how the OCTNs manage the ambiguity and lack of role clarity for their role (Cantini & Ells, 2007; Mueller, 2001; Mueller & Mamo, 2000, 2002; Wilkes & Beale, 2005).

Figuring It Out

The majority of the previous research identifies the obligations and behaviors expected in the professional practice of clinical trial nurses (CTNs), more specifically oncology clinical trial nurses (OCTNs). The ANA and IACRN (2016) *Scope and Standards* and the ONS (2016) OCTN Competencies provide principals, domains, standards, responsibilities, and competencies for the specialty practice.

Despite the literature defining the role, the participants in this study still believed they were *Implementing an Undefined Job.* The OCTNs has to *figure out* their position, learn from those experiences, and apply that knowledge to future circumstances they encountered in their practice. The OCTNs *figured out* their position by using the strategies of *learning as you go*, *utilizing their assets*, s*tanding their ground*, and *managing hope.*

Learning As You Go

The overall consensus of the OCTNs was there was a lack of training for their position and the training varied from institution to institution and department to department. *Learning as you go* gave the OCTNs perspective about the training, or the lack of training, for their profession of managing oncology clinical trials. Although the OCTNs were required to have at least two years of experience in order to participate in this present research study, the OCTNs relied on various additional resources to *figure out* their position when they started their position and when they were confronted with a new ethical challenge in their practice.

Learning as you go expands upon Mueller and Mamo's (2002) discovery that many clinical trial nurses (CTNs) learned about their position on the job. In addition, this present research study reveals the creativity and resourcefulness of the OCTNs as they sought to

fulfill their undefined job responsibilities: they relied on OCTN colleagues, even when their colleagues seemed busy with their own duties; they depended on locating additional resources to enhance their knowledge about additional treatments; and the OCTNs trusted the research protocol for direction on how to manage a patient while on a clinical trial.

The Oncology Nursing Society (ONS) (2016) identified the behaviors for a new OCTN to advance from the novice OCTN phase to an experienced OCTN. ONS (2016) determined this normally occurred after two years of experience in the position, depending on the work environment and the OCTN's involvement in continuing education. However, the literature is lacking on educational programs for OCTNs and processes which can enhance understanding about the OCTN position.

A recent publication by Showalter, Cline, Yunglas, La Frenz, Stafford, and Maresh (2017) gave an administrative report on a Research Nurse Residency Program for nursing school graduates. The authors describe a 12-month residency program with research-specific training and protocol-specific training for the OCTN residents. The initial results from nurse residents' experiences were positive, but there was no information from the OCTN residents' experiences when they were confronted with ethical challenges in their new professional role.

Utilizing Their Assets

When the OCTNs were confronted with ethical challenges in practice, they *figured out* how to *Implement an Undefined Job* by *utilizing their assets.* The OCTNs in this research study *figured out* what assets they could bring to their patient receiving investigational treatment as the patient's nurse and when they needed to call on other professionals for assistance. The literature describes a clinical trial nurse (CTN) as a

professional nurse functioning within the domain of the practice of nursing and a nurse performing professional duties in medicine by implementing medical research protocols (Mueller, 2001; Mueller & Mamo, 2002). This study revealed the OCTNs did not describe themselves as practicing in the domain of medicine. Instead, when the OCTNs were confronted with ethical challenges, they understood the boundaries of their nursing practice and acted accordingly by *utilizing their assets*.

Often, the OCTNs believed they were the best asset as a nurse in *utilizing their assets* for the patient: The OCTNs performed comprehensive patient assessments to monitor for side effects of experimental treatment; they provided education to the patient throughout the clinical trial; they formed relationships with the patients by listening, being empathetic, and understanding the patient in an effort to gather data to help the patient.

The OCTNs also sought out assistance from other professionals with additional knowledge and talents that would assist their patient. They reached out to physicians when patients inquired about their treatment regimen, to licensed medical professionals who could write for prescription drugs to alleviate side effects, or to social workers who could support patients in need of assistance. This finding is similar to those of Di Giulo et al. (1996) research which acknowledged the clinical trial nurse (CTN) requires good communication with other professionals to ensure for the continuity of care for their patient on a clinical trial.

Standing Their Ground

The OCTNs in this present research study *figured out* how to *Implement an Undefined Job* by responding with a basic nursing principle: protect the patient. The OCTNs protected their patient or protected their research protocol by *standing their*

ground. The OCTNs would *stand their ground* if they believed their patient's safety was threatened during the clinical trial process. They would also *stand their ground* if they believed the quality or integrity of their clinical trial was threatened.

The literature states a clinical trial nurse (CTN) has an ethical responsibility to advocate for the rights and safety of research participants and to ensure the standards of social justice (ANA & IACRN, 2016). The OCTNs in the present study encountered numerous situations where it was necessary for them to *stand their ground* to protect their patient's rights even if it involved risk to their professional position. The study findings add to previous literature describing the nurse as someone with the moral obligation to act as the patient's advocate and support the patient's healthcare needs (Oberle and Allen, 2006).

Other authors have commented that the role of the clinical trial nurse (CTN) as a patient's advocate has the potential to interfere with a clinical trial (Cantini & Ells, 2007; Oberle & Allen, 2006). The oncology clinical trial nurses (OCTNs) in this study *stood their ground* as their patient's advocate even when it interfered with the procedures in the clinical trial protocol. For example, they refused to take a blood sample from a comatose patient as requested by the company sponsoring the clinical trial; they *stood their ground* to physicians and refused to enroll patients who did not meet the clinical trial's eligibility criteria; and they *stood their ground* when physicians pressured them to enroll and start treatment before the results of the protocol screening criteria were known.

Managing Hope

Managing hope was an additional strategy the OCTNs used in order to *figure out* how to *Implement an Undefined Job*. The strategy of *managing hope* is new and has not

been discussed in the previous literature review. Gold, Chambers, and Dvorak (1995) understood nurses as using diplomacy on when to act when they considered the various desires of the physician, patient, and nurse. The authors stated, "In deciding, they want to prevent harm and feel comfortable with the decision" (p.140).

The OCTNs *managed hope* by being truthful with the patient about the possibilities of treatment offered by the clinical trial. They also *managed hope* by understanding and supporting their patient's decision to be in the clinical trial. *Managing hope* revealed the OCTNs negotiated a delicate balance of the possibility of a patient's last chance at treatment, the patient's desire for success of this treatment, as well as the physician's expectations of the treatment. The OCTNs *managed hope*: by balancing the reality of the patient's cancer diagnosis with the possibilities offered by treatment on a clinical trial; by being honest with the patients about possible deadly side effects; and by recognizing the additional burdens participation in a clinical trial can be for a patient or the patient's family.

Informed Consent

The informed consent process was the area the oncology clinical trial nurse (OCTNs) reported encountering the most ethically challenging issues. The role of the clinical trial nurse (CTN) in the informed consent process is addressed in both the Scope and Standards (ANA & IACRN, 2016) and the OCTN Competencies (ONS, 2016) as a vital responsibility of the CTN. It is necessary for the CTN to ensure the research participant understands the study and is able to make an informed decision to voluntarily participate in the investigational treatment. The informed consent process should be a shared activity between the physician and the CTN (Chamorro & Appelbaum, 1988; Cisar & Bell, 1995; Di Giulio et al., 1996; Hubbard, 1982; Kaempfer, 1982; McEvoy, Cannon

& MacDermott, 1991; Ocker & Plank, 2000). Nevertheless, several participants in this research study revealed variability in how the informed consent process was conducted. Some of the OCTNs did not participate in the informed consent process because the physician performed the informed consent, while other OCTNs complete the entire informed consent process with a patient after the physician introduced the clinical trial and left the patient's room. The present study supports the role of the CTNs as cited by Sadler, Lantz, Fullerton, and Dault (1999) which calls for the CTN to be an advocate for the patient by making patients effective partners in the informed consent process.

Chamorro and Appelbaum (1988) agree that ethical dilemmas are likely to arise for CTNs during the informed consent process because the burden of the patient understanding the informed consent is the nurse's responsibility. The oncology clinical trial nurses (OCTNs) in the study described multiple occasions when the burden of the patient's understanding of the informed consent fell on their shoulders. The OCTNs confronted these ethical challenges by: *standing their ground* if they believed a patient was not capable of consenting for experimental treatment; they *stood their ground* if they thought the patient was not in a state of mind to knowingly consent for investigational treatment and; they *utilized their assets* and redirected medical questions to the physicians when they patients asked them questions about the investigational research they did not feel qualified to answer.

Demographics and Education

The literature suggests a baccalaureate degree as the minimum educational requirement for a clinical trial nurse (CTN) (ANA & IACRN, 2016). However, three out of the 12 participants in this study had a diploma degree in nursing. The literature also

indicates specialty practice certification is an additional level of education oncology clinical trial nurses (OCTNs) can obtain to demonstrate a mastery of skills and knowledge (ANA & IACRN, 2016). Two research specialty certifications were identified concerning clinical research, although the certifications were not specific to nursing. Only three OCTN participants were certified as Certified Clinical Research Professionals (CCRP), a certification through the Society of Clinical Research Associates (SOCRA). Three OCTN participants did not hold any certification while seven participants held certifications outside the specialty of clinical research.

ANA and IACRN (2016) state much of the education the CTNs takes place through mentoring, workshops, conferences, training, or professional organizations. *Learning as you go* revealed that generally the OCTNs did not feel prepared for their position. The participants relied on colleagues, principal investigators, and research nurse managers for assistance to *Implement an Undefined Job*. The OCTNs were also creative in locating additional resources such as books, the internet, and additional policies in an effort to *figure out* the position. Despite the supplementary training and resources, the OCTNs still felt unprepared to carry out their duties especially when confronted with ethically challenging situations.

IMPLICATIONS OF THE STUDY

The present study has important implications to the professional practice of clinical trial nurses (CTNs), and more specifically, oncology clinical trial nurses (OCTNs). The substantive theory, *Implementing an Undefined Job*, emerged from data which reflected the experiences of OCTNs and the ethical challenges they encountered in their professional

practice. The theory has implications for the professional practice of OCTNs in the areas of practice and education.

Implications for Practice

The substantive theory, *Implementing an Undefined Job*, enhances the literature about CTNs, particularly OCTNs, in providing exceptional care to their patients. The study reveals the OCTNs' commitment to their patient's safety and their dedication to provide the patient with quality care while receiving experimental treatment on a clinical trial. The *Clinical Research Nursing: Scope and Standards of Clinical Practice* (American Nurses Association & International Association of Clinical Research Nurses, 2016) and Oncology Clinical Trial Nurse (OCTN) Competencies (Oncology Nursing Society, 2016) provide a robust foundation for the OCTN's professional practice. However, the *Scope and Standards* (ANA & IACRN, 2016) and the OCTN Competencies (ONS, 2016) do not provide guidance on the moment-to-moment, patient-to-patient situations the OCTNs encounter in their professional practice.

The substantive theory, *Implementing an Undefined Job*, highlights the difficulties the OCTNs encounter in the day-to-day, patient-to-patient situations when they were confronted with ethical challenges in practice. The present study revealed the OCTNs demonstrated extreme ingenuity in finding ways to meet their patients' needs during treatment on a clinical trial because the OCTNs believed they had an obligation to protect their patient and look out for their patient's well-being. The OCTNs relied on colleagues and additional resources such as the research protocol, other books, the internet, lecture series, or institutional and departmental policies as effective methods to *figure out* how to

Implement an Undefined Job. These resources are essential to novice and experienced OCTNs and should be made available as references for them to access in their position.

The present study also showed the OCTNs' commitment to protect the integrity of the clinical trial they managed, as a method to their commitment to protect their patient. The OCTNs routinely encountered physicians who did not observe the rules of the research protocol, specifically in the area of the patient enrollment inclusion criteria. The inclusion criterion is precisely designed for each protocol with the intent to protect the volunteer patients and protect the study data. More emphasis should be given on physicians following the inclusion criteria despite particular patient or physician situations in order to bypass the criteria for a patient's enrollment in a specific study. If the inclusion criterion for each protocol is strictly followed, the study would result in more reliable and reproducible scientific results of investigational oncology treatment. Institutions or departments should create policies to ensure the inclusion criterion is upheld in an effort to protect the patient and the study data.

In addition, the present study revealed significant variability in the informed consent process. The process varied from institution to institution, department to department, and among the study participants in how the patients were informed about the trial, who provided information about the trial, who answered the patient's questions, and who obtained the patient's agreement to participate in the investigational clinical trial. The informed consent process created many ethically challenging situations the OCTNs had to *figure out* how to navigate. Ideally, the informed consent process should be consistent across institutions and departments. The principal investigator or physician and the OCTN should be in the patient's room at the same time to answer questions and obtain the patient's

informed consent to participate in a clinical trial. Each member of the research team brings a unique understanding of the treatment and the requirements of the clinical trial and can assist patients in making the most informed decision for their treatment regimen.

Implications for Education

An important implication of this study is the need for educational programs for the oncology clinical trial nurse (OCTN). Since there is little or no information about the position of a clinical trial nurse (CTN) in current nursing baccalaureate programs, the first training a new OCTN receives is generally institutionally or departmentally based. Furthermore, the study suggests the need for an institutional or departmental dedicated OCTN educator to oversee the entire training process for the novice OCTN. The study gives insight into the necessity that novice OCTNs have the basic knowledge and skills to fulfill the responsibilities of the new role before being assigned to manage research protocols and patients independently.

After the institution or departmental introductory training, the novice OCTN relies on education from the protocol or a mentor. The education the OCTNs receives is inconsistent because the training varies according to the institution, department, protocol, or mentor. In addition, the OCTNs' experiences give insight into the need for a program to ensure the novice OCTN has a reliable mentor. New OCTNs need to be assigned to a mentor who is available to provide guidance about the new role. If novice OCTN mentors are overloaded with their own protocols or patient loads, the mentors are unable to provide the novice OCTN with an effective and meaningful training experience.

Study findings also reveal the need for experienced OCTNs to receive continuing professional development. Continuing educational opportunities for clinical trial nurses

(CTNs) is limited (ANA & IACRN, 2016) and there is an immediate need for education to be available to this specialty practice, especially concerning the subject of ethics. In addition, institutions or departments should create libraries of resources online for OCTNs to reference when navigating the day-to-day, patient-to-patient implementation of their professional position.

Furthermore, experienced OCTNs would benefit from the creation of a specialty practice certification in clinical research nursing. The only research certifications available at the time of this study are offered by the Association of Clinical Research Professionals (ACRP) and the Society of Clinical Research Associates (SOCRA); these certifications are available to all clinical research professionals. Although both organizations and certifications acknowledge the unique framework surrounding clinical research, but they are not specific to the role of the nurse in clinical research. Similarly, a degree for a Masters in Clinical Research exists in various graduate programs, but the degree is open to all clinical research professionals. At the time of this study, Drexler University was identified as the only graduate program to offer a degree for a Masters of Nursing in Clinical Trials Research. A certification or expanded graduate programs unique to nurses and the specialty practice of clinical trial nurses (CTNs) would help to develop and demonstrate a CTNs mastery of the skills and knowledge of their clinical practice.

STUDY SIGNIFICANCE

The findings of this Classical Grounded Theory (CGT) study reveal the perspectives of oncology clinical trial nurses (OCTNs) in managing ethical challenges in professional practice. The study findings provide important information about the practice of oncology nurses who manage clinical trials. The study is the first qualitative study to

examine the perspectives of OCTNs and the ethical challenges they encounter in their professional practice through the development of the substantive theory, *Implementing an Undefined Job*. The study findings have significant implications for the training, practice, and education of OCTNs. The themes of *learning as you go, utilizing their assets, standing their ground,* and *managing hope* could be used to inform novice OCTNs in how to confront ethical challenges in their practice. Although the study only focused on OCTNs, the substantive theory, *Implementing an Undefined Job*, could be applied to clinical trial nurses (CTNs) in other fields who manage clinical trials.

STRENGTHS AND LIMITATIONS

Several strengths and limitations can be identified in this Classical Grounded Theory (CGT) (Glaser, 1978, 1998, 2005, 2011, 2012, 2013, 2014, 2015) study. The strengths of this study included the rigorous, inductive research approach of CGT which allowed the researcher to explore the ethical challenges and experiences of oncology clinical trial nurses (OCTNs) first-hand, which resulted in rich data to examine. The CGT methods, data collection procedures, and data analysis processes allow the data to "speak for itself" (Glaser, 1998, p. 8). This study was the first study to examine the ethical challenges of OCTNs and the study findings resulted in the first substantive theory addressing the management of those ethical challenges by OCTNs. Moreover, the substantive theory has the potential to be developed into a formal theory. In addition, the study utilized an online website for data collection which allowed participants to engage with the researcher from a wide geographic range.

There are also limitations to the study, including the study sample. The 12 nurses who participated in the study were self-selected, thus the study results only reflected the

opinions and experiences of the nurses who participated. The business cards and website used to recruit participants asked for nurses to share experiences about ethical challenges in practice, which might have limited a more diverse group of participants willing to share their personal experiences. In addition, the study only examined the specialty practice of OCTNs. Clinical trial nurses (CTNs) practice in a variety of other expertise fields which could limit the generalization of the study findings.

SUGGESTIONS FOR FUTURE RESEARCH

Further research can be directed to develop the substantive theory, *Implementing an Undefined Job*, into a formal theory. Additional research also could explore the issues revealed in the present study, such as the training of novice OCTNs, the informed consent process, or the development of a certification or Master's program specifically for clinical trial nurses CTNs. Further research could also be conducted to evaluate how the novice OCTNs manage ethical challenges in professional practice and strategies they use to handle these issues.

In addition, the strategies discovered in the research findings of how the OCTNs *figured out* how to *Implement an Undefined Job* could be examined in greater detail. Research could be completed on the nurses' impulse to *stand their ground* and how doing this might influence their practice or professional relationship with physicians. Furthermore, research could be performed on the theme of *managing hope* and evaluate how OCTNs balance the patient's level of hope or the physician's level of hope with an experimental cancer treatment. Results from the suggested studies would contribute to the development of the substantive theory, *Implementing an Undefined Job*, into a formal theory.

CONCLUSIONS

This Classical Grounded Theory (CGT) (Glaser, 1978, 1998, 2005, 2011, 2012, 2013, 2014, 2015) study explored the ethical challenges experienced by oncology clinical trial nurses (OCTN) in their professional practice. The study was the first qualitative study to examine OCTNs and ethical challenges resulting in the substantive theory, *Implementing an Undefined Job*, which is resolved by the OCTN *figuring it out*, by the actions of *learning as you go, utilizing their assets, standing their ground,* or *managing hope.* The substantive theory has implications for the professional practice and education of oncology clinical trial nurses (OCTNs) and also has indications for future research into other specialty practice areas of clinical trial nurses (CTNs).

Appendix A: IRB Approval Letter

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Institutional Review Board
301 University Blvd.
Galveston, TX 77550-0158
409.266.9475

02-Sep-2016

MEMORANDUM

TO: Sheryl Forbes
Grad School Biomedical Science GSBS9999

FROM: Janak Patel, MD
Institutional Review Board, Chairman

RE: Initial Study Approval

IRB #: IRB # 16-0202

TITLE: Ethical Challenges Faced by Oncology Nurses Managing Clinical Trials A Classical Grounded Theory Study

DOCUMENTS: Appendices A-I, electronic consent form, demographic questions, interview questions, protocol

The UTMB Institutional Review Board (IRB) reviewed the above referenced research protocol via an expedited review procedure on **02-Sep-2016** in accordance with 45 CFR 46.110(a)-b(1). Having met all applicable requirements, the research protocol is approved for a period of 12 months. The approval period for this research protocol begins on **02-Sep-2016** and lasts until **02-Sep-2017**.

The requirement to obtain informed consent is waived in accordance with 45 CFR 46.116(d).

The research protocol cannot continue beyond the approval period without continuing review and approval by the IRB. In order to avoid a lapse in IRB approval, the Principal Investigator must apply for continuing review of the protocol and related documents before the expiration date. A reminder will be sent to you approximately 90 days prior to the expiration date.

The approved number of subjects/medical records/specimens to be enrolled/utilized is **25.00**. If, the approved number needs to be increased, you first must obtain permission from the IRB to increase the approved sample size.

Appendix B: Website Home Page

Are you an oncology nurse who manages clinical trials?

Are you willing to participate in an online research study regarding your perspectives on ethical challenges experienced in your practice?

If you are interested, please contact:

Sheryl Forbes, MEd, BSN, RN, CCRP
University of Texas Medical Branch Doctoral Nursing Program
SGForbes@UTMB.edu
713-805-3833

Appendix C: Website Purpose Link

Oncology Clinical Trial Nurses and Ethical Challenges is a study to examine the oncology clinical trial nurses perspectives on ethical challenges in their practice. The study is a qualitative design using online synchronous interviews.

The researcher aims to learn more about the nurse's perceptions of ethical issues and examine how the issues are resolved. The study will give a voice to oncology clinical trial nurses in the everyday management of clinical trials.

Appendix D: Website Participant Link

If you are interested in participating in the study, please understand your participation is voluntary. You may choose not to participate at any time during the study.

In order to be eligible to participate, you must meet the following criteria:

1. Be a registered nurse (RN) licensed to work in the United States,
2. Be practicing as an oncology clinical trial research nurse for at least two years,
3. Able to speak and write English
4. Have access to a computer to participate in online interviews

Appendix E: Website Anonymous Link

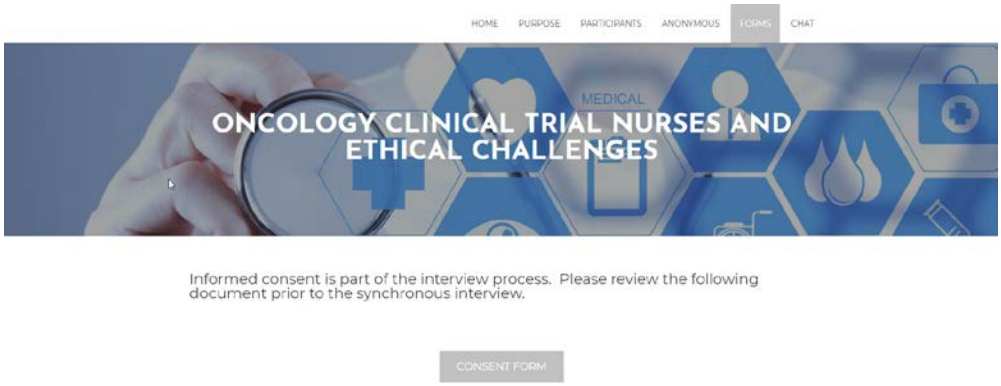
The primary risk to participants in this study is loss of confidentiality. You can prevent this risk with two steps:

1) Create an anonymous email address to contact the researcher by email.

Go to mail.google.com. Create a new account. Set up a pseudonym email to protect your identity. Use your favorite color, favorite flower, favorite food, and a combination of four numbers when creating your first and last name. Use this email address to contact the researcher if you do not want to use your personal email account. If you call Sheryl to set up an online interview, dial *67 prior to dialing the number. This will block your number from being displayed.

2) If you call Sheryl to set up an online interview, dial *67 prior to dialing the number. This will block your number from being displayed.

Appendix F: Website Forms Link



Appendix G: Website Consent Link

The University of Texas Medical Branch at Galveston
Minimal Risk Consent Form

Protocol Title: Ethical Challenges Faced by Oncology Nurses Managing Clinical Trials
IRB Number: **16-0202**

Principal Investigator: **SHERYL FORBES, MED, BSN, RN, CCRP**
Phone: 713-805-3833
Email: SGForbes@UTMB.edu

Why am I being asked to take part in this research study?
You are being asked to take part in this study because you are a registered nurse currently practicing as an oncology clinical trial nurse for at least two years. Your participation in this study is completely voluntary. You may refuse to participate or stop your participation in this research study at any time without penalty.

What is the purpose of this research study?
The purpose of this study is to enhance the understanding of ethical situations encountered by oncology clinical trial nurses.

What procedures are involved as part of this research study?
The anticipated number of subjects involved in the study will be less than 25 participants. You will be asked to participate in one online synchronous data collection session which will not last over 90 minutes.

What extra tests and procedures will I have if I take part in this study?
If the researcher believes another session is necessary for further information, she will ask you if you would be willing to schedule a second online session at your convenience; that session will not last over 30 minutes.

What are the possible risks for choosing to participate in this research study?
The potential risks of participation in the study are loss of confidentiality and emotional distress. To protect your privacy, a participant code will be used instead of your name and any information that might identify you will be removed or masked. In the event you become emotionally distressed during data collection, we will pause or discontinue data collection.

What are the potential benefits for participating in this research study?
If you agree to take part in this study, there may be no direct benefits to you. We hope the information learned from this study will benefit other oncology clinical trial nurses in the future.

Is there an alternative treatment/procedure?

The alternative is not to participate in the study.

How will my information be protected?
All results obtained in this study will be kept confidential and only available to the research study team. Your individual information will not be reported, only the results of all participants as a group.

How will my privacy be protected?
To protect your privacy, a Participant code number will be used instead of your name and any information that might possibly identify you will be removed or masked.

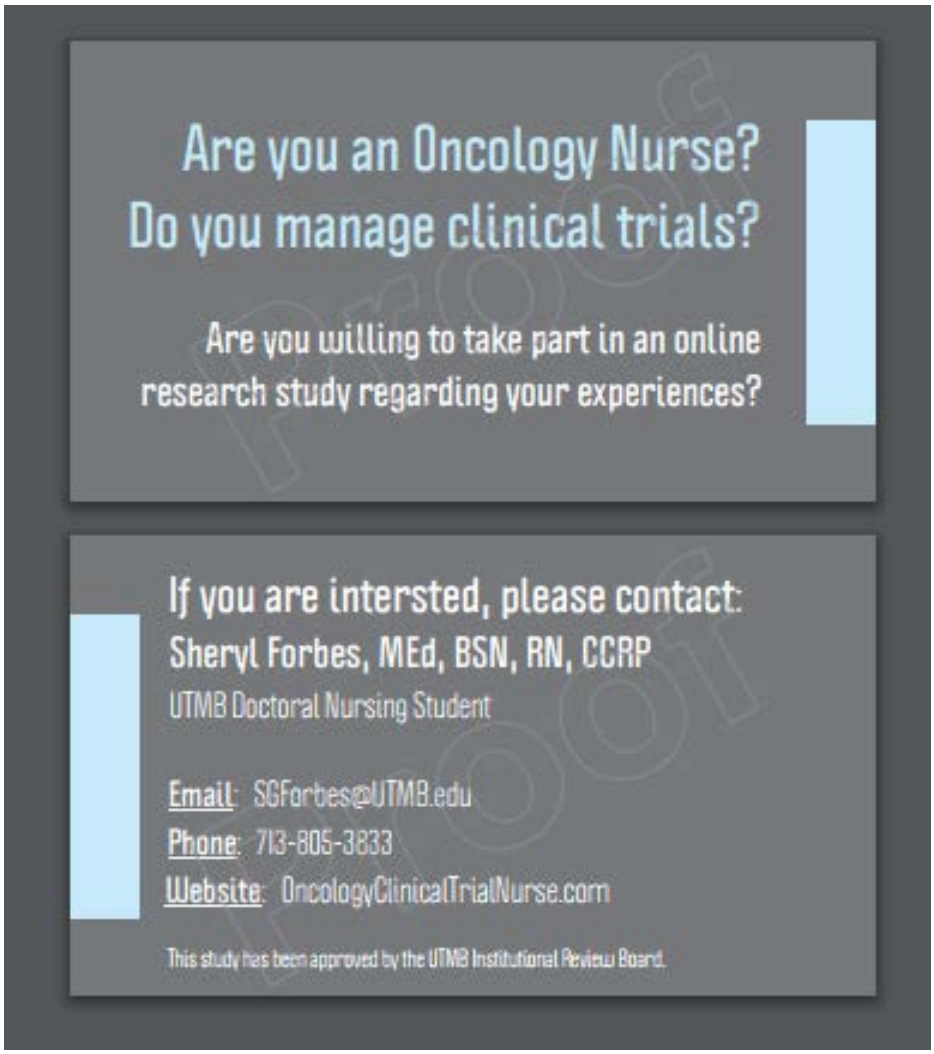
Who can I contact with questions about this Research study?
If you have any questions, concerns or complaints before, during or after the research study, or if you need to report a research related injury or bad side effect, you should immediately contact Sheryl Forbes, MEd, BSN, RN, CCRP at 713-805-3833 or Carolyn Phillips, PhD, RN at 409-772-8234.

This study has been approved by the Institutional Review Board. If you have any complaints, concerns, input or questions regarding your rights as a subject participating in this research study or you would like more information about the protection of human subjects in research, you may contact the Institutional Review Board Office, at (409) 266-9475 or irb@utmb.edu.

CONSENT TO PARTICIPATE:
The purpose of this research study, procedures to be followed, risks and benefits have been explained to you. You have been given the opportunity to ask questions, and your questions have been answered to your satisfaction. You have been told who to contact if you have additional questions. By signing this form, you are confirming that you have read this consent form and voluntarily agree to participate as a subject in this study.

Appendix H: Website Chat Link

Appendix I: Business Cards



Appendix J: Email to Colleagues

Dear Colleague:

I am looking for volunteers to participate in my research study exploring oncology clinical trial nurses experiences' with ethical challenges. My study title is: “Ethical Challenges Faced by Oncology Nurses Who Manage Clinical Trials: A Classical Grounded Theory Study.” I would like to interview Oncology clinical trial nurses who are:

1. Registered nurses
2. Have been practicing as a part-time or full-time oncology clinical trial research nurse for at least two years

Eligible nurses will participate in a typed online synchronous interview scheduled at your convenience.

If you are interested in sharing your insights and perspectives about your experiences managing clinical trials, find out more information on the following website: www.OncologyClinicalTrialNurse.com

I appreciate your interest in my study and look forward to speaking with you.

Sincerely,

Sheryl Forbes, MEd, BSN, RN, CCRP
Principal Investigator
SGForbes@UTMB.edu

Appendix K: First Email to Potential Participant

Dear Colleague:

Thank you for your interest in participating in my study. Have you had a chance to review the website with more information about the study? (www.OncologyClinicalTrialNurse.com) Do you have any questions about the study or participating?

The "interview" is online and will not take longer than 90 minutes. You need computer access during that time preferably in an area where you will not be interrupted.

Would you like to set up a time for an interview? Take a look at your calendar and let me know three options that work for you (in order of preference).

Once we confirm a time, I will send you an email with a unique password for our interview with instructions on how to log into the website under the tab labeled "chat."

Thank you again for your interest in participating! I look forward to setting up a time for an interview.

Sincerely,

Sheryl Forbes, MEd, BSN, RN, CCRP
Principal Investigator
SGForbes@UTMB.edu

Appendix L: Email with Instructions and Password to Participant

Dear Study Participant:

Thank you for your interest in being a Study Participant in my research project "Ethical Challenges Faced by Oncology Nurses Who Manage Clinical Trials: A Classical Grounded Theory Study."

This email serves as a reminder of our scheduled online interview. During the interview, I will discuss the study, obtain your agreement to participate, collect demographic and interview data.

Prior to our online interview, please review the informed consent found on the website at www.OncologyClinicalTrialNurse.com.

Our interview is scheduled for

Date: DATE
Time: TIME

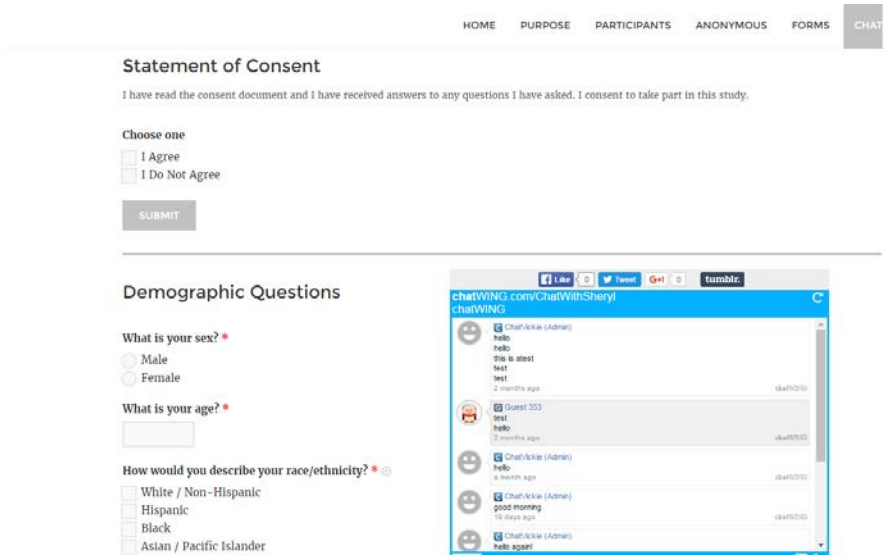
About five minutes prior to the interview, please go to the website at www.OncologyClinicalTrialNurse.com and click on "Chat." When prompted, type in the following password: UNIQUE PASSWORD. This password will be active only during our scheduled interview time.

If for any reason this date or time is no longer convenient for you, please notify me via email at your earliest convenience. Again, I greatly appreciate your interest and look forward to talking to you online.

Sincerely,

Sheryl Forbes, MEd, BSN, RN, CCRP
Principal Investigator
SGForbes@UTMB.edu

Appendix M: Statement of Consent



Appendix N: Demographic Questions

What is your sex?

- Male
- Female

What is your age?

How would you describe your race/ethnicity?

- White / Non-Hispanic
- Hispanic
- Black
- Asian / Pacific Islander
- American Indian / Alaskan Native
- Other

What is your highest degree level in the field of nursing?

- Diploma
- Bachelors
- Masters
- Doctorate

How many years have you been a registered nurse?

How many years have you been a clinical trial nurse?

How many years have you been an oncology clinical trial nurse?

Do you hold a nursing certification? (Y/N)

If yes, what certification(s)?

Did you receive any training for your position as a clinical trial nurse? If so, please describe.

Appendix O: Interview Questions

Introduction Question:

1. What does the phrase “ethically challenging” mean to you?

Grand Tour Question:

1. Tell me about a challenging ethical situation you have encountered during your experience as an oncology clinical trial nurse.
2. What’s it like being an oncology clinical trial nurse?

Probing Questions:

1. Tell me more about …
2. Please give me an example of …
3. Describe what you meant when you said …
4. During what phase of the clinical study did this challenge occur?

Concluding Questions:

1. Is there anything else you would like to share with me about your experiences as a clinical trial nurse?
2. May I contact you for additional questions in the future?
3. If you think of anything else you would like to add, please contact me at SGForbes@UTMB.edu or 713-805-3833.

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Vita

Sheryl Guiney Forbes was born on November 9, 1979 in Webster, Texas to Edward and Glynda Guiney. Sheryl received a Bachelor of Science in Anthropology from the University of Houston in 2002. She went on to receive a Masters in Science Education from the University of Houston in 2005. She taught high school biology for three years in Houston before she went back to school for a degree in Nursing. She received a Bachelor of Science in Nursing from the University of Texas Health Science Center Houston in 2009. Sheryl immediately began her nursing career in the Intensive Care Unit at M.D. Anderson Cancer Center in Houston, Texas, where she learned about the care and treatment of the oncology patient during a critical point in their hospital stay. In 2013, she transitioned to the position of a lymphoma research nurse, caring for lymphoma patients enrolled in clinical trials. In this position, Sheryl collaborated with physicians and study sponsors to provide quality care to the clinical trial patient and serve as a guide to the patient's safe participation in clinical research. She has co-authored numerous publications evaluating the results, side effect management, or nursing interventions in lymphoma clinical trials. Sheryl serves as an elected representative of multiple nursing committees at M.D. Anderson Cancer Center which evaluate the clinical practice nursing standards, ensure high standards of professionalism, and enhance the specialty practice of the clinical trial nurse. Sheryl is the wife of Scott Forbes and mother to two remarkable, champion children, Ethan Forbes and Isaac Forbes.

Permanent address: 13730 Slate Mountain Lane, Houston, Texas 77044

This dissertation was typed by Sheryl Guiney Forbes