Spring 2007

Oncology Nurses' Attitudes toward Cancer Clinical Trials and Their Perceptions of Patients' Understanding

Paul D'Amico

ONCOLOGY NURSES' ATTITUDES TOWARD CANCER CLINICAL TRIALS AND THEIR PERCEPTIONS OF PATIENTS' UNDERSTANDING

by

Paul G. D'Amico

BSN, Adelphi University, 1984

MS, State University of New York at Stony Brook, 1996

Submitted to the Doctoral Program Faculty

of the School of Nursing in Partial fulfillment

of the Requirements for the Degree of

Doctor of Philosophy in Nursing

Duquesne University

2007

DUQUESNE UNIVERSITY
SCHOOL OF NURSING

PhD PROGRAM

APPROVAL OF FINAL DEFENSE OF DISSERTATION

STUDENT: Paul G. D'Amico

DATE OF ADMISSION: Fall, 2003

DISSERTATION TITLE: Oncology Nurses' Attitudes Toward Cancer Clinical Trials and Their Perceptions of Patients' Understanding

---

DISSERTATION COMMITTEE:

	Type name below	*Signature*	*Date*
Dissertation Chair:	Dr. Gladys Husted	Gladys J. Husted	3/21/07
Internal Member:	Dr. Joan Such Lockhart	Joan Such Lockhart	3/21/07
External Member:	Dr. Anne R. Bavier	Anne R. Bavier	March 21, 2007
External Member:	Dr. Heidi Ehrenberger	Heidi Ehrenberger	3/21/07

Approved by Dissertation Chair and Committee

Joan Such Lockhart

Joan Such Lockhart, PhD, RN, CORLN, AOCN®, CNE, FAAN
Professor & Associate Dean for Academic Affairs

3/21/07
Date

- ☐ Student Copy
- ☐ Dissertation Chair Copy
- ☐ Student File Copy

ABSTRACT

ONCOLOGY NURSES' ATTITUDES TOWARD CANCER CLINICAL TRIALS AND THEIR PERCEPTIONS OF PATIENTS' UNDERSTANDING

by

Paul G. D'Amico

Duquesne University

Clinical trials in oncology that evaluate new cancer treatments are essential. However, in the United States only 2%-4% of eligible adult cancer patients participate in the National Cancer Institute's clinical trials annually. Oncology nurses have a major role in the care of patients contemplating enrollment into cancer clinical trials, yet little is known about their attitudes, beliefs, and perceptions.

The Modified Nursing Attitude Survey and a demographic form were used to collect data. This study discovered significant predictors to attitudes and perceptions; however, all R^2 (coefficient of determination) values were very low, which indicates that some other unknown variables could be better predictors than those used in this study. On average, oncology nurses reported positive attitudes towards cancer clinical trials. However, statistically significant differences were found between nurses grouped by primary work setting and primary position. Additionally, as a whole, these nurses perceived that patients have enough information to make decisions regarding clinical trial participation, but they somewhat disagreed that: clinical research should be conducted only in cancer centers, oncologists and nurses put too much pressure on patients to participate, and patients are often unaware that their treatment is part of a research protocol. Significant differences in these perceptions were found between: primary work

setting, number of years in cancer nursing, and whether or not the nurse works with these patients. Consistent with prior research, oncology nurses perceive that experimental cancer treatments should have a large benefit before being offered. Moreover, there were statistically significant differences in this perceived benefit among the nurses grouped by number of years in cancer nursing, primary work setting, and education level. More research is needed to explore the reasons for these differences in attitudes and perceptions.

This study explored nurses' attitudes and perceptions regarding cancer clinical trials. Since their attitudes may ultimately dictate their behaviors towards clinical trials, this study has far reaching implications for nursing education, nursing practice, and the conduct of clinical trials. By investigating oncology nurses' attitudes and perceptions toward cancel clinical trials this study begins to assess the behavior of oncology nurses towards cancer patients.

Dissertation Advisor: Gladys L. Husted, PhD, RN

ACKNOWLEDGEMENTS

I wish to thank my wife and my best friend, Cindy D'Amico, who supported me through the entire educational program and dissertation process. A special thanks to each member of the committee: Dr. Gladys L. Husted, Dr. Joan Lockhart, Dr. Anne Bavier and Dr. Heidi Ehrenberger. They provided guidance and direction that enriched this work: Permission to use and modify the survey instrument was given by Dr. Neil Meropol, who always was available to answer questions. Dr. Elizabeth Pearman provided me with expert statistical help, as well as, knowledge and skills along the process, no question was ever to trivial for her.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURE

CHAPTER I: INTRODUCTION

A. Background

History of Human Subject Research

Experiments performed by the Nazis on concentration-camp inmates are some of the most well-known atrocities to date. Out of this horror came the first formalized set of ethical rules for the conduct of human experimentation. In the aftermath of the war, the Nuremberg Tribunal prosecuted the perpetrators and, in 1946, developed a set of ethical principles that have come to be known as the Nuremberg Code. The Code sets out 10 ethical principles for the conduct of clinical trials. The first is the most important: "The voluntary consent of the human subject is absolutely essential." Moreover, this consent must be obtained "without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion" (Nuremberg Military Tribunal, 1949, p. 181).

In June 1966, Henry K. Beecher, an anesthesiologist at Harvard Medical School, published an article entitled "Ethics and Clinical Research" in the *New England Journal of Medicine* (Beecher, 1966). In his article, he listed more than 22 clinical trials that appeared to be highly unethical, in which investigators risked their patients' lives without fully informing them of the dangers and without obtaining their permission. The "Ethics and Clinical Research" article had a significant role in the development of requirements for informed consent of research subjects.

In 1970, the Tuskegee experiment was revealed. Starting in 1930 and continuing for four decades, investigators began examining, but not treating, a group of 400 African-American men who had syphilis. The investigators were interested in watching the

natural course of the disease. In 1930, the existing treatments for syphilis were complex and not very effective, so the investigators felt they were justified in not treating the men. Penicillin as a highly effective cure for syphilis became available widely in 1945. However, many of the men were left untreated until the situation was uncovered in 1970 (Finn, 1999).

The publicity from the Tuskegee Syphilis Study prompted the National Research Act of 1974 that created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Cancer Institute, 1979). One charge to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines to assure that such research is conducted in accordance with those principles (Public Law 93-348, 1974).

In carrying out the above charge, the Commission was directed to consider the following: the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine; the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects; appropriate guidelines for the selection of human subjects for participation in such research; and the nature and definition of informed consent in various research settings (National Cancer Institute, 1979).

The Belmont Report summarizes the basic ethical principles identified by the Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Cancer Institute, 1979). It is the outgrowth of an intensive four day period of discussions held in February 1976 at the Smithsonian Institution‘s Belmont

Conference Center and supplemented by monthly deliberations of the Commission that were held over a period of nearly 4 years. It is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects (Office of Behavioral and Social Sciences Research, 2003).

The three basic ethical principles for the conduct of clinical trials discussed in the Belmont Report are respect for persons, beneficence, and justice (National Institutes of Health, 1979). In applying those principles, the authors recommended that consideration be given to three requirements:

1. Informed consent: In order to provide fully informed consent, a potential research subject must first be given full information about the research project. Second, that information must be presented in a comprehensible way, taking into account the patient‘s intellectual capacities. Third, the consent must be truly voluntary, and free from coercion and undue influence.

2. Assessment of risks and benefits: The dangers of any clinical trial must not exceed its potential benefits.

3. Selection of subjects: There must be fair procedures for the selection of research subjects (National Institutes of Health, 1979).

Therapeutic Clinical Trials

A clinical trial is clinical research “designed to answer a question that has therapeutic implications for patients” (Hubbard, 1985, p. 67). The most familiar clinical trials in oncology are the ones that evaluate new methods of screening, prevention, diagnosis, or treatment of cancer (National Institutes of Health, 2006). Clinical trials are

generally divided into four main phases. Each has a separate and particular goal, and each successive phase builds upon the previous one (Grady, 1991).

Phase I studies. Phase I studies are unblinded and uncontrolled. They are designed to evaluate the maximum tolerated dose (MTD) and the safety of a new drug or combination of drugs and a given administration schedule in human subjects (Johansen, Mayer, & Hoover, 1991; Yoder, O'Rourke, Etnyre, Spears, & Brown, 1997). MTD and treatment schedule are the endpoints of a Phase I trial, thus antitumor or disease response may not be noted (Jenkins & Hubbard, 1991; Johansen et al., 1991).

Patients eligible for these trials are generally those with less than three months to live and have no alternative available treatment options. Some patients will receive a treatment which has no benefit to them, since these trials offer no guarantee of efficacy. However, there is an important characteristic that can be of value to patients. There is the possibility that the new treatment, which looks promising in the laboratory, may continue to invoke its same promising characteristics in humans (Sadler, Lantz, Fullerton, & Dault, 1999). These trials offer patients a ray of hope even though the Phase I trial is concerned only with establishing the MTD. Qualitative studies conducted with patients enrolled into Phase I clinical trials discovered hope as a recurrent theme (Cox, 1999; Cox & Avis, 1996; Moore, 2001; Schutta & Burnett, 2000; Yoder et al., 1997).

Phase II studies. At the completion of a Phase I study, the MTD is established. It is at this dose level that Phase II studies are designed to determine the activity and efficacy of a drug or treatment against a specific disease. The timing and frequency of objective tumor measurements before, during, and after treatment must be specified and strictly followed (Sadler et al., 1999).

If the findings from the Phase II study show promise that the intervention is equivalent to, or better than, currently available therapies, then the intervention is moved into Phase III evaluation.

Phase III studies. Once a medication demonstrates efficacy in Phase II testing, Phase II studies are conducted. Phase III studies are large randomized, controlled studies (they may be blinded, but not always) designed to test the investigational agent(s) against the accepted standards of care. Survival, quality-of-life, and cost-effectiveness are assessed in a Phase III trial (Jenkins & Hubbard, 1991).

Patients who are eligible for a Phase III clinical trial typically are at an earlier stage of diagnosis than in previous phases, and conform to narrowly defined inclusion and exclusion criteria for participation (Sadler et al., 1999).

At the completion of a Phase III trial there will be a more thorough understanding of the new therapies' benefits and potential adverse reactions. Upon successful completion of a Phase III trail, the sponsor of the trial (pharmaceutical company, or government agency, etc.) can request Food and Drug Administration (FDA) approval to market the therapy for the specified condition evaluated in the trial (Sadler et al., 1999).

Phase IV studies. After a treatment receives FDA approval, Phase IV studies, commonly known as post-marketing studies, are conducted. They "assess the rate of serious side effects and evaluate additional therapeutic uses of the therapy" (Grady, Cummings, & Hulley, 2001 p. 170). These studies could include, but would not be limited to, examining different doses or schedules of administration than were previously used in Phase II studies, use of the drug in other patient populations or other stages of the disease, or use of the drug over longer time periods to assess long-term safety.

B. The Problem

The majority of advances in cancer treatment come in small steps achieved through clinical trials in which new drugs and treatments are carefully studied on human subjects. Thus, the ethics of research, especially regarding the rights of patients, becomes vital to this endeavor. Clinical trials are an important step in helping translate potentially beneficial basic research findings into clinical practice (Grunfeld, Zitelsberger, Coristine, & Aspelund, 2002). It is vital to recruit as many eligible patients as possible for studies, and to do so in an ethical manner. Clinical trials in oncology that evaluate new treatments are essential. However, in the United States (US) only two to four percent (N = 28,000-56,000) of all newly diagnosed adult cancer patients annually participate in National Cancer Institute (NCI) clinical trials (Lara, et al., 2001). This is despite estimates that 12%–44% (N = 168,000-616,000) of adults with cancer are eligible for entry (Morrow, Hickok, & Burish, 1994). According to the NCI, this is in sharp contrast to the enrollment of pediatric cancer patients into clinical trials, which approaches 50-80% (N = 6,200 – 9920) (Ries, et al., 1999; Sateren, et al., 2002). This strong enrollment of children with cancer is due in part to the fact that most children are treated at academic medical centers with experts' in pediatric oncology (Sateren, et al., 2002).

A total of 1,399,790 new cancer cases and 564,830 deaths from cancer are expected in the U.S. in 2006 (Jemal, et al., 2006). This is a greater concern when age-adjusted death rates are considered. Cancer in the U.S is the leading cause of death among men and women under age 85 (Jemal, et al., 2006). A total of 476,844 people under age 85 died from cancer in the U.S. in 2003, compared with 436,258 deaths from heart disease (Jemal, et al., 2006). Therefore, recruitment and retention of adult

participants into oncology clinical trials is critical to the outcome and success of clinical trial research. However, concerns exist about the ability of clinical investigators to provide sufficient information to patients regarding research trial participation so that patients can recognize the distinction between research and therapy (Bok, 1995). The shortage of clinical trial participants often results in early trial closure, increased cost, compromised generalizability of the findings, and delays in the development and adoption of new treatments (Barrett, 2002).

Today, the vast majority of clinical trials relate to treatment decisions. When patients consider treatments, they base their decisions upon many factors, including available information (Llewellyn-Thomas, McGreal, & Theil, 1995). Nealon, Blumberg, and Brown (1985) reported on an unpublished NCI pilot study investigating the educational needs of cancer patients considering clinical trials and to develop ways to meet these needs. At the time there were few educational materials that explained clinical trials to patients and families. The NCI conducted an assessment with the following participants ($N = 53$): 16 cancer patients currently in trials and 4 family members, 4 NCI cancer control staff, 18 physicians (7 NCI staff and 11 community physicians), 8 oncology nurses, 2 oncology social workers, and 1 health educator (Nealon, Blumberg, & Brown, 1985). Patients reported that although they do not know what to ask, when they do ask questions, they are more likely to ask a nurse than a doctor. Therefore, patients considering investigational therapy may receive much of their information about options from nurses. From the experience of this investigator, this remains true today. It is ethically essential for healthcare professionals to provide patients with the information required to promote informed decisions (Beauchamp & Childress, 2001).

Oncology nurses participate in all aspects of clinical trials as direct care givers, research nurses, research partners, and primary investigators. They also administer experimental agents to patients, manage side effects, and obtain informed consent (Ehrenberger & Lillington, 2004; Joshi & Ehrenberger, 2001; Rosse & Krebs, 1999). Oncology nurses have a major role in cancer clinical trials, such as direct caregivers, patient advocates, educators, counselors, as well as facilitators of clinical trials. Yet, not much is known about their attitudes, beliefs, and perceptions.

C. Purpose

The purpose of this study was to examine oncology nurses' attitudes toward cancer clinical trials and to identify nurses' perceptions of patients' understanding of the clinical trial process and desire for information and, reasons for patient participation in clinical research. This study investigated factors which may influence oncology nurses' attitudes and perceptions. They included the nurses' age, educational preparation, length of time in oncology nursing, whether of not the nurse actually cares for patients contemplating enrollment or currently enrolled in a clinical trial, primary position, and work setting.

D. Research Questions

The following research questions guided this inquiry:

1. What are oncology nurses' attitudes toward the benefits of cancer clinical trials?

2. What are nurses attitudes about how effective a research drug or experimental therapy should be shown to be before it is offered to patients?

3. What are the nurses' perceptions regarding patients' understanding and knowledge of the treatment regimen?

4. What factors do nurses perceive influence a patient's decision to participate in a cancer clinical trial?

5. What are nurses' perceptions of patients' decision-making processes and the desire for information regarding clinical trial participation?

6. What are the perceptions of nurses regarding where clinical research should be conducted and the role of oncologists and nurses in clinical trials?

7. Do the demographic variables of age, education level, number of years in oncology, whether or not the nurse actually works with patients contemplating enrollment or currently enrolled in a clinical trial, primary work setting, and primary position of oncology nurses serve as significant predictors of attitudes and perceptions as measured by the modified Nurse's Attitude Survey (NAS)?

E. Definition of Terms

The key terms used throughout the research were operationalized and defined as follows:

Oncology Nurses

Conceptual definition: A person skilled or trained in "treating human responses of patients and families with cancer diagnoses or who are at risk for developing cancer. It encompasses the role of direct caregiver, educator, consultant, administrator, and investigator" (Oncology Nursing Society [ONS], 2004, p. 7).

Operational definition: Registered nurses (RNs) who are members of the Oncology Nursing Society (ONS) who reside in the United States only, who permit ONS

to release their addresses, who self-report that they are employed full, or part-time, and self-report their primary functional area as patient care or research and self-report a primary position other than researcher/principal investigator.

Attitudes

Conceptual definition: "Summary evaluations of objects (e.g., oneself, other people, issues, etc.) along a dimension ranging from positive to negative" (Petty, Wegener, & Fabrigar, 1997, p. 611). The evaluations of these psychological objects are captured in such attribute dimensions as good-bad, harmful-beneficial, pleasant-unpleasant, and likable-dislikable (Ajzen, 2001; Ajzen & Fishbein, 2000). Attitudes are made up of the beliefs that persons accumulate over their lifetimes (past experiences).

Operational definition: For this study, attitude was measured as the mental position oncology nurses have with regard to the importance of conducting clinical research in oncology. Specifically, their agreement or disagreement with statements that clinical research improves patient care, is important for future standards of care in oncology, encourages patients' to participate in research, and the patients' preferences to be treated on a clinical trial, as measured on the NAS (Burnett, et al., 2001; see Appendix A).

Perceptions

Conceptual definition: A representation of one's reality, with a process of interpreting information from sensory data and memory, that gives meaning to one's experience and influences one's behavior (King, 1981).

Operational definition: Perceptions were measured as oncology nurses' perceptions of patients' understanding of cancer clinical trials, treatment of their cancer,

and their desire for information. Specifically, the nurse's agreement or disagreement with statements that patients are well informed regarding participation in clinical trials, patients' awareness that their treatment is part of a research protocol, patients' understand their treatment plans and prognoses, and patients desire to be informed as reported on the NAS (Appendix A).

Cancer Clinical Trials

Conceptual definition: A type of research study that tests how well new medical approaches work in people. These studies test new methods of screening, prevention, diagnosis, or treatment of cancer (NCI, 2006). This includes any study that is provided in the context of a research protocol, which has been approved by an Institutional Review Board (IRB) and where a patient has signed an informed consent document. This includes Phase I, II, III, and IV clinical trials.

Operational definition: A cancer clinical trial was defined as any study testing a method of cancer treatment. Moreover, a study that is provided in the context of a research protocol, which was approved by an IRB and patients have signed informed consent documents. This includes Phase I, II, III, and IV clinical trials.

F. Assumptions and Limitations

Assumptions

The following assumptions were made:

1. There is variation among individual nurses' knowledge regarding cancer clinical trials.

2. There is no deceit or coercion, when nurses provide patients with information and education regarding cancer clinical trials.

3. Nurses responded honestly to all questions.

Limitations

The limitations of the study were:

1. Response bias may have existed using a survey method of data collection (Dillman, 2000). It is unknown if people who responded to the survey may be different from those who do not.

2. Individuals may have provided socially desirable responses. They may have responded in a particular manner, regardless of what is a fair representation of their attitudes or perceptions.

3. The sample of oncology nurses who were recruited from the ONS membership may not represent all cancer nurses in the nation.

G. Significance

Clinical trials are essential to bring potentially beneficial basic research into clinical practice and provide new methods of screening, prevention, diagnosis, or treatment of cancer (Grunfeld, et al., 2002; NCI, 2006). In the U.S., very small percentages (2-4%) of adult cancer patients participate in clinical trials (Lara, et al., 2001) despite estimates that 12-44% of patients are eligible (Morrow, et al., 2004). Therefore, there are more patients who could, but do not, participate in cancer clinical trials. This shortage of clinical trial participants compromises the generalizability of findings and delays development and adoption of new cancer treatments (Barrett, 2002). The delays potentially could be detrimental to patients with a cancer diagnoses.

Oncology nurses have a key role in the clinical and research settings by serving as direct caregivers, patient advocates, educators, counselors, as well as facilitators of

clinical trials. As such, nurses have a major role in cancer clinical trials, yet not much is known about their attitudes and perceptions on this subject. Only one study was reported addressing nurses' attitudes toward cancer clinical trials. Burnett et al. (2001) addressed nurses' attitudes toward cancer clinical trials in a comprehensive cancer center. The investigators conducted a descriptive study with a 59-item self-report survey. The objective was to identify nurses' attitudes and beliefs toward cancer clinical trials and their perceptions about factors influencing patients' participation. Four hundred seventeen nurses employed at a NCI-designated cancer center were surveyed, and 250 nurses (60%) responded. The authors found 96% of nurses reported that participation in clinical trials is important to improving standards of care; however, only 56% of nurses believed that cancer patients should be encouraged to participate in trials and 35% of nurses reported that they would prefer treatment in a clinical trial if they had cancer.

This discrepancy is alarming considering that patients considering enrollment into a clinical trial or presently are enrolled in one, receive important information about treatment options from nurses. Additionally, NCI investigators found that many cancer patients may not know what to ask, but, when they do, they are more likely to ask a nurse than a physician (Nealon, Blumberg, & Brown, 1985). Oncology nurses' attitudes and perceptions are important factors that impact upon the nurses' role in patient care. Additionally, attitudes and perceptions impacts professional nursing issues, such as nursing practice and nursing education. Nurses' attitudes and perceptions regarding cancer clinical trials ultimately may dictate their behaviors towards patients enrolled in or contemplating enrollment in such trials. By investigating oncology nurses attitudes and

perceptions toward cancer clinical trials this, study begins to assess the behavior of oncology nurses towards cancer patients.

There is a paucity of research that addresses nurses' attitudes and perceptions towards clinical trials. This is curious, since nurses administer the experimental agents used in clinical trials and provide direct care for these patients and their families. Most literature regarding attitudes and perceptions of cancer clinical trials has focused on the attitudes and understanding of physicians, patients, and the public (Cassilith, Lusk, Miller, & Hurwitz, 1982; Comis, Miller, Aldigé, Krebs, & Stoval, 2003; Daugherty et al., 1995; Ellis, Bulow, Tattersall, Dunn, & Houssami, 2001; Meropol, et al., 2003). There is an important gap in knowledge regarding oncology nurses' attitudes and perceptions towards cancer clinical trials, the clinical trial process, and informational need of potential research participants.

It is hoped that the results gained from this study will begin to close the gap in knowledge and add to nurses' understanding of clinical trials. This study potentially identified discrepancies between the majority of nurses' reporting that research is important for advancing oncology standards of care and the smaller number who actually recommend a research protocol to a patient.

CHAPTER II: REVIEW OF THE LITERATURE

The following review of the literature provided the theoretical and research background for the issues that are addressed by the research questions. Despite an extensive literature search of published works (CINAHL, MEDLINE, PsycINFO, EBM Reviews, Health and Psychosocial Instruments database, ProQuest Digital Dissertations), with Medical Subject Headings (MeSH) search terms, "nurses' attitudes", "nurses' perceptions'", and "cancer clinical trials", only one study was found regarding nurses' attitudes and perceptions of cancer clinical trials (Burnett et al., 2001). Consequently, this literature review consists mainly of findings from related studies.

First, the organizing framework that guided this study is discussed, as well as a review of healthcare literature incorporating the framework. Additionally, its relevance to the proposed research explained. Next, a review of literature pertaining to attitudes and perceptions related to clinical trials is discussed. Finally, the role of the oncology nurse in the context of the care of patients enrolled in, or contemplating enrollment into, cancer clinical trials is explained.

A. Organizing Framework

Ajzen's and Fishbein's (1980) Theory of Reasoned Action (TRA) provides the framework that guided this study. The roots of the theory come from the field of social psychology. Social psychology attempts, among other things, to explain how and why attitude impacts behavior. Beginning in the 1930s, psychologists began to argue actively about what components should comprise the attitude concept. Although there was agreement that all attitudes contain an evaluative component, theorists disagreed about whether beliefs (cognitions) and behaviors should be included within the attitude concept.

The prevailing view among cognitive social psychologists was that "attitude" has both affective and belief components and that attitudes and behavior should be consistent (e.g., people with positive attitudes should behave positively toward the attitude object; Ajzen & Fishbein, 1980).

Social psychologists theorized that attitude included behavior and cognition and that attitude and behavior positively were correlated. In 1935, Gordon Allport proposed that the attitude-behavior concept was multi –dimensional, rather than unidimensional, as previously thought (Allport, 1935; Azjen & Fishbein, 1980). Attitudes, as part of the attitude-behavior concept, are multi dimensional systems consisting of beliefs about the attitude object, feelings about the attitude object, and action tendencies toward the object (Azjen & Fishbein, 1980).

One of the most famous early studies conducted by sociologist Richard LaPiere, was studying if people behave consistently with their attitudes. LaPiere traveled across the United States with a Chinese couple. The group stopped at over 200 hotels and restaurants, where the Chinese couple was refused service at only one location. Six months later, LaPiere wrote to these same establishments inquiring as to whether or not they served Chinese guests. The responses he received indicated that 92% of the establishments did not accommodate Chinese guests (LaPiere, 1934). LaPiere concluded that different sets of social forces influenced attitudes and behaviors. This showed a contradiction between the attitude responses to the letter and the actual behavior toward the Chinese couple (Fazio & Roskos-Ewoldsen, 1994). This study demonstrated that, attitude was not a good predictor of behavior. By the late 1960s, social psychologists no longer believed they had a theory to explain the relationship between attitude and

behavior. It was in this context that Ajzen and Fishbein created the Theory of Reasoned Action (1967). The theory proposes that personal attitudes have a major influence on the intent to engage in different behaviors (Ajzen & Fishbein, 1980). The theory views men and women as a rational organisms utilizing information at their disposal to judge, evaluate, and decide his course of action. Therefore, the intent towards choosing a given behavior is a function of an individual's attitude towards the behavior.

Attitudes are composed of the beliefs that individuals accumulate over their lifetime. Some beliefs are formed from direct experience, some are from outside information, and others are inferred, or self-generated. However, only a few of these beliefs actually influence attitude. These beliefs are called "salient beliefs" and are the "immediate determinants of a person's attitude" (Ajzen & Fishbein, 1980, p. 63). An attitude, then, is an individual's salient belief about whether the outcome of their actions will be positive or negative. If individuals have positive salient beliefs about the outcome of their behavior, then they are said to have a positive attitudes about the behavior. And, vice-versa, if individuals have negative salient beliefs about the outcome of their behavior, they are said to have negative attitudes. The beliefs are rated for the probability that engaging in the behavior will produce the believed outcome. This is called the "belief strength." These two factors, belief strength and the evaluation, are then multiplied to give the attitude (Ajzen & Fishbein).

The TRA attempts to predict human behavior, based on concepts of personal beliefs, attitude towards the behavior, perceived beliefs of others, and subjective norms (see Figure 1).

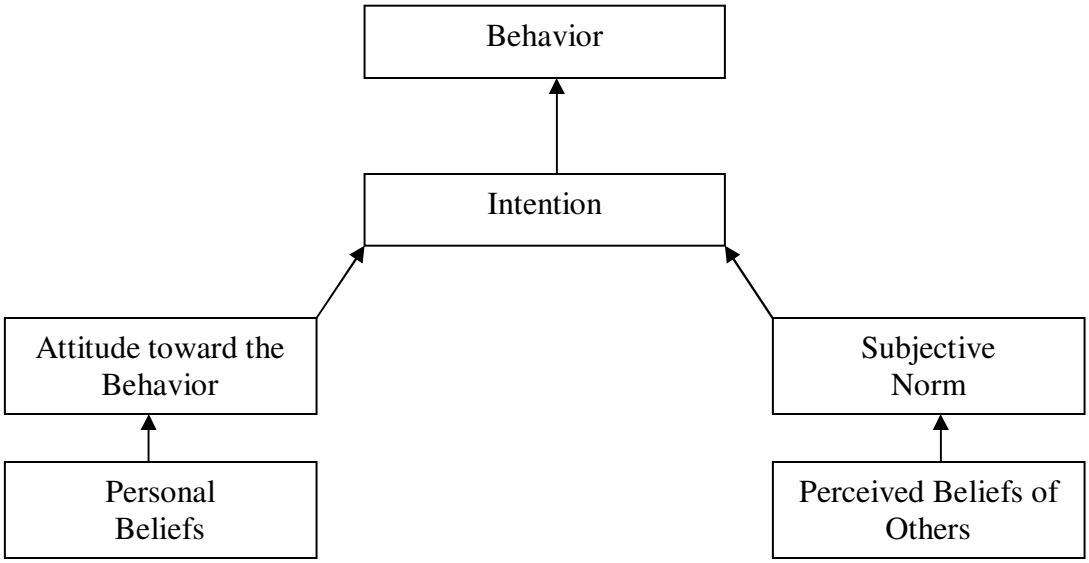

Figure 1. Model of reasoned action. (Ajzen & Fishbein, 1980)

Therefore, an individual's belief could ultimately determine one's attitudes, intentions and behaviors. In combination, attitude toward the behavior, subjective norm, and perception of behavioral control lead to the formation of behavioral intention (Ajzen, 2001). As a general rule, the more favorable the attitude and subjective norm, and the greater the perceived control, the stronger should be the person's intention to perform the behavior in question. Finally, given a sufficient degree of actual control over the behavior, people are expected to fulfill their intentions when the opportunity arises (Ajzen, 2001). A person's intention, then, becomes a function of personal and social influence. Both attitudinal and subjective factors are important determinants of intention, but the relative weight of each component varies with the individual (Ajzen & Fishbein, 1980). As suggested by its name, the TRA proposes that people engage in a deliberate and thoughtful process in deciding how to behave (Sanbonmatsu & Fazio, 1990).

This study focused on the attitudes of oncology nurses towards cancer clinical trials and their perceptions of patient understanding and reasons for patient participation

in clinical research. Concepts of the theory define the nurse's own beliefs, as well as, the perceived beliefs of those groups that are in a position to influence the ideas and actions of the nurse. These beliefs and actions pertain to the nurse's relationship with the patient contemplating enrollment or already enrolled in a cancer clinical trial. Therefore, the combination of the nurse's beliefs and the group belief could lead one to action, depending upon which set of beliefs are more valued (or is perceived to lead to a positive outcome) by the nurse, thus forming an attitude on the part of the nurse.

One way to begin to assess the actions of nurses towards patients is to investigate their attitudes. The nurses' attitudes regarding cancer clinical trials may ultimately dictate their behavior towards patients enrolled in or contemplating enrollment in a cancer clinical trial. Within the practice of oncology nursing, these behaviors can include direct patient care, coordination of care, patient education, and patient advocacy.

In this study the measurement of attitudes (and perceptions) were assessed via a Likert scale to discern positive and negative attitudes. Having negative attitudes towards cancer clinical trials may impact the nurse's objectivity in his/her role as patient educator or patient advocate and determine the nurse's behavior in these situations. Nurses perceive their roles differently from other healthcare professionals in that, in addition to focusing on clinical judgments and decision making, they concentrate on patient advocacy and caring (Krisjansdottir, 1992). This caring focus enables nurses to ensure adequate communication with patients about treatment regimens. Nurses may be more aware of patients' attitudes towards clinical trial research, because of the unique patient-nurse relationship. Nurses' attitudes may influence patient's opinions regarding participation

and may reflect patients concerns in this area. The nursing role and type of caring focus outlined above are all part of the nurse-patient relationship.

B. The Use of the TRA in Health Care Literature

Nursing Research Examining Attitudes

In nursing research the TRA has been shown to be a viable theory examining the attitudes of nurses and patients. Renfroe, O'Sullivan, and Mcgee (1990) developed a causal model, using the components of the TRA, for explaining nursing documentation behavior. They utilized the TRA to assess the relationship of nurses' attitudes, subjective norms, and behavioral intentions to their documentation behaviors. Subjective norm is defined as a "person's assessment of whether or not people important to him or her feel the behavior should be performed" (Ajzen, 2001, p. 32). Behavioral intention is related to attitudes and subjective norms. The more favorable the attitude and subjective norm, and the greater the perceived control, the stronger the person's intention should be to perform the behavior in question (Ajzen). The purpose of the study was to develop and test the TRA that explained documentation behavior of nurses. A convenience sample of all staff nurses ($N = 108$) at three different hospitals, on all units (excluding emergency room, operating room, labor and delivery, and psychiatric units) within three hospitals in the Southeast was used. The authors collected data using a questionnaire that they developed to measure each component of the causal model, attitude, subjective norm, behavioral intent, and documentation behavior. Prior to shift report, each nurse completed the questionnaire and returned it to investigators. After the shift, the investigators returned to the unit to score the documentation for one patient assigned to each nurse that shift. Documentation behavior "was based on what should be documented in any hospitalized

patient's chart during an eight hour shift" (Renfroe, O'Sullivan, and Mcgee, 1990, p.52). Attitude toward documentation did not relate significantly to intention to document optimally. Subjective norms had a significant effect on behavioral intent. Attitude and subjective norm accounted for 46.1% of the variance in behavioral intent. Behavioral intent had a significant effect on documentation behavior, accounting for 15.2% of the variance. It appears that subjective norm, which is the influence of others, directs the intention to document and thus relates to subsequent documentation. The authors' recommendations for practice, based on the study findings, include the communication of high ideals and expectations of important others to the staff nurse to improve the documentation quality.

Using the TRA as a theoretical framework for their study, Stuppy, Armstrong, and Casals-Ariet (1998) examined the attitudes of health care providers, medical and nursing students ($N = 513$) towards tattooed adults and adolescents. This was a descriptive correlational, comparative study, with a demographic form and the Armstrong Tattoo Scale (ATS) distributed to convenience samples of physicians, registered nurses, licensed vocational nurses, and medical and nursing students. The ATS is a semantic differential scale consisting of 16 contrasting adjectives representing beliefs about persons with tattoos. Items for the ATS were generated from the clinical experience of the investigators, interviews with tattoo artists, tattooed people, and from the literature. Adjective pairs on the ATS included such items as ugly-beautiful, impulsive-deliberate and crude-refined. Each item was scored from 1 (strongly agree at the negative end) to 7 (strongly agree at the positive end). Data were coded so that a higher score reflected more positive attitudes. Possible scores ranged from 16 to 112, when responses to all items

were summed. An expert panel of doctorally prepared faculty investigators and sociologists reviewed the instrument for content validity. A pilot study with 161 nursing students determined initial construct validity. Exploratory principal component analysis indicated that 10 items represented an evaluation dimension and six items related to an activity dimension about attitudes toward tattooed persons. Respondents were asked to record their attitudes towards five groups of people. Groups to be rated were professional men, nonprofessional men, professional women, nonprofessional women and adolescents (13–18 years old). The type of tattooed person to be rated was listed as the heading for the 16 item ATS (e.g., "Professional women who have tattoos are . . ."). For the five groups internal consistency reliability of the ATS ranged from a Cronbach's alpha of 0.92 to 0.95. The authors found no respondent group had mean scores reflecting a positive attitude towards tattooed persons. This study suggests that tattooed persons, especially adolescents, may be at risk of being negatively perceived, when they seek health care.

Clarke and Aish (2002) explored the health beliefs and attitudes of a group of smokers with vascular disease who participated in a smoking cessation program (Group 1) and a group who declined participation (Group 2). The authors used Ajzen and Fishbein's TRA, Keeney's Expected Utility Decision Theory (Keeney, 1992), and Prochaska and DiClemente's Transtheoretical Model of Change (DiClemente, 1997) to describe the influence of this smoking cessation program on beliefs and attitudes about smoking in Group 1. Smokers completed a smoking beliefs questionnaire with vascular disease at baseline and after 13 weeks of a smoking cessation intervention. Smokers who did not want to participate in the smoking cessation program also completed this questionnaire (Group 2). Statistically significant differences differentiated people who

enrolled in the smoking cessation program from those who did not. Subjects in Group 2 smoked less per day, were less educated, were less often diagnosed as having peripheral arterial disease, were found to be more in the precontemplation stage of change in smoking cessation, cared more about what their physician and family thought they should do, and perceived themselves to be at less risk for developing more severe circulatory problems if they did not quit smoking. After 13 weeks, participants in both Groups 1 and 2 were found to smoke significantly less per day. No support was found for the expectation that the smoking intervention would influence stage of change in smoking behavior or attitudes and beliefs about the risks of smoking to the participants' health after 13 weeks.

Nursing Research Examining Behaviors

The TRA has also been used in nursing research as a basis for studying the behaviors of nurses, healthcare workers, students, and patients. Selected college students (n = 256) and sexually transmitted disease (STD) clinic patients (n = 71) of the same age were compared for knowledge about AIDS, use of condoms, sexual behaviors and intentions to engage in various sexual practices (Strader & Beaman, 1991). The TRA model was used to elicit beliefs about condom use and significant referents that influence decisions on condom-use. Of the 256 college students, 87% were sexually active. College students had significantly fewer sexual partners in a 30-day period than STD patients, but in a 6-month period the mean number of sexual partners was the same for both groups. Significant difference was found in frequency of condom use for subjects with more than one partner. Among the college student sample, 60% did not use condoms compared with 32% of STD patients. Eighteen percent of college students reported intention to engage in

anal intercourse. No STD patients reported such intention. No statistical difference was found between groups on overall knowledge about AIDS and both groups manifested adequate knowledge of basic AIDS-related facts. Significant differences between groups were found in rank order of beliefs about using condoms as well as the referents that influenced decision-making. Beliefs about disease, pregnancy, worry, and the influences of sexual partners and friends had the strongest impact on college students. Sexual partners and mothers had a strong influence on STD patients' decisions-making, while "disease," "pregnancy," "decreases feeling" and "decreases partner's pleasure" were among the beliefs influencing condom use.

Miller, Wikoff, and Hiatt (1992) tested five variables of the TRA. The variables measured were attitudes, perceived beliefs of others, motivation to comply, intentions, and compliance behavior. The purpose of the study was to test the sufficiency of these variables to predict compliance with the medical regimen of hypertensive patients (N = 56). The subjects were a convenience sample of patients at an outpatient Veterans Administration (VA) Medical Center hypertensive clinic. The authors used the Miller Attitude Scale (Miller, Wikoff, McMahon, Garrett, & Johnson, 1982) to measure favorable and unfavorable attitudes towards performing medical regimen prescriptions. The Perceived Belief of Others Scale (Miller, Johnson, Garrett, Wikoff, & McMahon, 1982) was used to assess the subjects' beliefs about which prescriptions of the medical regimen people thought were most important to them and to which they should be compliant. The Motivation to Comply Scale (Ajzen & Fishbein, 1980) was used to measure motivation to comply with the regimen's prescription. Intentions were measured by the Health Intention Scale designed to assess subjects' intentions to perform the

medical regimen. Finally, behavior was measured by the Health Behavior Scale which measured subjects' compliance to the medical regimen. The authors reported the results using the Pearson Product moment correlations among the five variables (attitudes, perceived beliefs of others, motivation to comply, intentions, and compliance behavior). The results demonstrated the TRA sufficient for the prescriptions of diet, smoking, activity and stress, but not for medication. Findings indicated that compliance behavior was directly influenced by intention which, in turn, was influenced directly by attitude and motivation to comply and, indirectly, by perceived beliefs of others and were mediated by motivation to comply with the prescriptions of diet, activity, smoking, and stress. For the medication prescription, attitude and motivation to comply directly influenced regimen compliance.

Dunkle and Hyde (1995) used the TRA to identify factors that influence physical therapist and registered nurse (RN) students' intentions toward working with elderly individuals. Based on the TRA a survey instrument was developed to assess student intention to work with elderly individuals and factors influencing this intention. Later graduates were contacted to determine whether job selection matched intention. For all students, factors influencing intention were students' attitudes and students' perceptions regarding their families' expectations about the students' working with elderly persons. Intention had a positive correlation with job selection. Important underlying beliefs influencing students' attitudes, include the advantages of getting to know elderly patients and their families and caring for pleasant patients. The authors concluded that the results support using a theory-based model to identify predictors of job selection among physical therapist and nursing graduates.

The TRA and the Theory of Planned Behavior (TPB), another theoretical model by Ajken and Fishbein, were tested as predictors of health care workers' glove use when there is a potential for blood exposure (Levin, 1999). The TPB is an extension to the TRA and includes and additional element of "perceived behavioral control," in order to account for situations where an individual has less than complete control over the behavior. Perceived behavioral control indicates that a person's motivation is influenced by the perceived difficulty of the behaviors, as well as the perception of how successfully the individual can, or can not, perform the activity. If individuals hold strong control beliefs about the existence of factors that will facilitate a behavior, then they will have high perceived control over a behavior. Conversely, individuals will have a low perception of control if they hold strong control beliefs that impede the behavior (Ajzen, 1985). Levin (1999) surveyed a random sample of nurses and laboratory workers (N = 527) who completed a 26-item questionnaire. Using structural equation modeling techniques, intention, attitude, and perceived risk were significant predictors of behavior. Perceived control and attitude were the significant determinants of intention. The TRA was the most parsimonious model, explaining 70% of the variance in glove use behavior. The TPB was a viable model to study behavior related to glove use and reducing workers' risks to blood borne diseases.

Poss (1999) developed a Spanish-language, quantitative research instrument designed to study Mexican migrant farm-workers participation in tuberculosis screening. The instrument was pilot tested with19 Mexican migrant farm-workers to study their tuberculosis screening behaviors. The Tuberculosis Interview Instrument (TII) was developed from the results of a qualitative study and concepts from a theoretical

framework consisting of a combination of the Health Belief Model (HBM) (Becker, Radius, & Rosenstock, 1978; Rosenstock, Strecher, & Becker, 1994) and the Theory of Reasoned Action (TRA). After its development, the TII was subjected to translation and back-translation procedures to insure the equivalency of the English and Spanish versions, and it was reviewed for content validity.

In another study, Poss (2000) recruited a convenience sample of Mexican migrant farm workers ($N = 206$), after a presentation of a tuberculosis education program, participants were followed during the administration and reading of tuberculosis skin tests. The purpose of the study was to analyze the relationship between variables (susceptibility, severity, barriers, benefits, cues to action, normative beliefs, subjective norm, attitude, and intention) from the HBM and the TRA and participation by Mexican migrant farm workers in a tuberculosis screening program. Participants were interviewed in Spanish by the principal investigator, using the TII. Most subjects were male, aged 18–27 years, and had less than a sixth-grade education. Of the 206 subjects, 152 (73.4%) received the skin test, 149 (98%) had the skin test read, and 44 (29.5%) had positive skin tests. Based on logistic regression analysis, the model that best predicted intention included cues to action, subjective norm, susceptibility, and attitude. Participation in screening was best predicted by a model containing only two variables, intention and susceptibility. In this study, logistic regression analysis revealed that a more parsimonious model than the full HBM and TRA model accurately predicted both intention and behavior. Kleier (2004) tested the TRA to determine the behavior of nurse practitioners (NPs) regarding teaching testicular self-examination (TSE). The researcher utilized an instrument, developed by Minnick (1980), to explore relationships between

variables that applied the concepts in the TRA. The variables were attitudes, perceptions of and motivation to comply with opinions of others, behavioral intention to teach TSE, and TSE teaching behavior. A cross-sectional, exploratory, mailed survey was used to survey a random sample of 1,490 members of the American Academy of Nurse Practitioners, 621 NPs responded. After eliminating surveys that were not usable because of missing data, final analyses were carried out on 532 surveys, for a response rate of 36%. The author concluded that NPs had positive attitudes toward teaching TSE and were engaged in such teaching. They perceived that other NPs, physicians, and patients also valued TSE teaching. Attitude, perception of and motivation to comply with the opinions of significant others, and behavioral intention were associated with each other and predictive of TSE-teaching behavior. The findings supported the explanatory and predictive ability of the TRA.

Nonresearch Articles

Additionally, review articles have been written citing the TRA in the development of models to predict health behaviors. Fleury (1992) reviewed the primary motivational theories that were used to explain cardiovascular risk reduction. Specifically, the application of the Heath Belief Model, Heath Promotion Model, the TRA, TPB, and Self-Efficacy Theory to the initiation and maintenance of cardiovascular health behavior was addressed.

In evaluating the behavioral aspects of clinical trials, Morrow, et al. (1994) reviewed the literature on accrual in oncology clinical trials to characterize the extent of the problem of low accrual, identify reasons for it, and suggest ways to improve it. The authors examined four theories of health behavior (the Health Belief Model, Subjective

Expected Utility Theory, Protection Motivation Theory, and the TRA) and found that all suggest central concepts involved in understanding patient health-related behavior.

McGahee, Kemp, and Tingen (2000) developed a model for smoking prevention in preteen children, because they determined the lack of a well-defined theoretical basis a weakness in the research conducted on smoking prevention programs designed for preteen children. The authors used the TRA as well as other literature to develop their model.

Finally, Poss (2001) discussed the development of a new model developed as the theoretical framework for an investigation of the factors affecting participation by Mexican migrant workers in tuberculosis screening. The new model was developed by synthesizing the Health Belief Model (HBM) and the TRA. Intention to take part in tuberculosis screening was best explained by a model containing four variables: subjective norm, attitude, susceptibility, and cues to action (operationalized as attendance at an educational program). The best model for predicting behavior (actual participation in screening) required only two variables: intention and susceptibility. In both cases, variables derived from both the HBM and the TRA were necessary to predict the dependent variable.

C. Attitudes and Perceptions

Attitudes and perceptions are related concepts. As previously defined (in chapter 1), attitudes are evaluations of psychological objects (e.g., oneself, other people, issues, etc.) captured in such attribute dimensions as good-bad, harmful-beneficial, pleasant-unpleasant, and likable-dislikable (Ajzen, 2001, Ajzen & Fishbein, 2000).

Perceptions are a representation of one's reality, with a process of interpreting information from sensory data and memory, which gives meaning to one's experience and influences one's behavior (King, 1981). It is the basis by which one's opinions or views are formed and, thereby, give rise to actions.

In the nurse-patient relationship, perception is a crucial component of the nurse's assessment of the patient and clinical situation (King, 1981). King states that nursing is "a process of human interactions between nurse and client whereby each perceives the other and the situation; and through communication, they set goals, explore means, and agree on means to achieving goals" (King, 1981, p. 144). The perceptions of the nurse must be in agreement with the patient's perceptions for mutual goal setting to occur. Only then can patients collaborate with the nurse to set goals, explore the means and agree on the strategies to attain mutual goals. The nurse must perceive accurately the patient and clinical situation to work toward a common goal.

Attitudes are perceptions that persons accumulates over their lifetime (past experiences). King also states that perceptions are related to factors such as past experiences and educational background (King, 1981). This suggests that perceptions are subjective in nature and, consequently, nurses' perceptions may be very different from the patients' perceptions. In this study the subjective nature of perception was explored as oncology nursing experience and education were analyzed as predictors that could influence perceptions and attitudes. Additionally, attitudes guide behavior, the more favorable the attitude and subjective norm, and the greater the perceived control, the stronger the person's intention to perform a behavior (Ajzen & Fishbein, 1980). According to King (1981), perceptions also influence behavior. As an example, the nurse

and patient meet in some situation, perceive each other, make judgments about each other, take some mental action, and react to each one's perceptions of the other (Gonot, 1989; King, 1981). When interactions lead to transactions, "goal attainment behaviors" are exhibited (King, 1981, p. 60). Underlying the interaction process is that reciprocally congruent behavior, which the behavior of one person influences the behavior of the other and visa versa (Gonot, 1989; King, 1981). Therefore, individuals' attitudes and perceptions influence their behavior.

As stated above, attitudes and perceptions are related and interconnected concepts. Beginning with experience, events occur, and those events have a real or imagined vital and affective meaning to individuals. That experience produces a set of structured or unstructured beliefs and expectations. The beliefs and expectations have a motivational force. The objects from which an individual forms a belief are that which an individual experiences. That which one experiences is, so to speak, the objective term of the process. The affective motivations and reactions to experience are the subjective terms of the process. These are the attitudes that emerge. One's attitudes consciously or unconsciously determine how one will perceive like experiences in the future (G. Husted, February 6, 2006, personal communication).

Attitudes and Decision Making

Attitudes were also studied as a base for decision-making in the psychology literature. Sanbonmatsu and Fazio (1990) examined the role of attitudes in memory-based decision-making. They conducted two experiments to represent some of the conditions under which attitudes guide memory-based decision making. Participants in both experiments were undergraduates fulfilling a requirement for an introductory psychology

course (Experiment 1, n = 98; Experiment 2, n = 270). Experiment 1 examined the effect of fear of invalidity (a motivational variable) and time pressure (an opportunity variable) on the likelihood that a memory-based decision will be guided by attitudes. The primary dependent measure for both experiments was the participants' decision as to which store they would shop for a camera. The general description of one store, "Smith's Department Store," was favorable with the exception of the camera department, which was unfavorable. The other stores general description, "Brown's Department Store," was unfavorable with the exception of the camera department, which was favorable. They made the decision to purchase a camera under high or low time pressure, and under conditions of high or low fear of invalidity. The results from experiment 1 revealed the majority of participants (81 out of 98) evaluated Smith's more positively than Brown's. A 2 x 2 (fear of invalidity X time pressure) between subjects analysis of variance (ANOVA) was performed on the subjects camera decisions. Participants' low in fear of invalidity were more likely to choose Smith's than participants experiencing high fear of invalidity. The authors concluded that as the motivation to make a correct decision or the opportunity to access the relevant available knowledge decreases, the likelihood of an attitude-based decision increases.

In contrast to Experiment 1, in Experiment 2, the participants explicitly were instructed to form differentiated attitudes toward each department of each store, as well as general attitudes toward each store. The difference between Experiment 1 and 2 was with the participants in the differentiated attitude condition. As in experiment 1 the majority of participants (231 out of 270) evaluated Smith's more positively than Brown's. The participants' camera shopping decisions were then evaluated using a 2 x 2

x 2 (differentiation X fear of invalidity X time pressure) using between-subjects ANOVA. The authors concluded that attitudes guide decisions, and hence behavior, by affecting one's appraisals (perceptions) of decision alternatives. Attitudes provide a ready means of "sizing up" or appraising objects and events (Sanbonmatsu & Fazio, 1990, p. 620). In the context of decisions, the authors found attitudes provided a ready assessment of choice alternatives and they enabled an individual to make a decision rapidly and effortlessly. They also state that if a behavior were to be based on a number of specific beliefs and attitudes, then measuring those beliefs and attitudes is an effective way of predicting behavior.

Nurses' Attitudes and Perceptions

The investigator was only aware of one study reported that addressed nurses' attitudes toward cancer clinical trials. Burnett, et al. (2001) addressed nurses' attitudes toward cancer clinical trials in a comprehensive cancer center. They conducted a descriptive study with a 59-item self report survey. The objective was to identify nurses' attitudes and beliefs toward cancer clinical trials and their perceptions about factors influencing patients' participation in these trials. Four hundred seventeen nurses employed at a NCI designated cancer center were surveyed, and 250 nurses (60%) responded. The authors found 96% of nurses reported that participation in clinical trials is important to improving standards of care; however, only 56% of nurses believed that patients should be encouraged to participate in cancer clinical trials. In multiple regression analyses, older age (40 years of age or older) and being a research nurse were significant predictors of positive attitudes toward clinical trials. Work setting also was a significant predictor of nurses' perceptions of patients' understanding of treatment.

Research nurses had the highest mean score (23.2 out of 30) compared to intensive care unit/bone marrow transplant (ICU/BMT) nurses, who had the lowest mean score (18.6 out of 30; $p = 0.0001$). Overall, nurses reported that an investigational therapy should have at least a 50% chance of success prior to being offered to patients. The authors' recommendations for future research were to replicate the study with other comprehensive cancer center nurses, to conduct a study with nurses from settings other than comprehensive cancer centers, to compare the findings between the groups, and to study current nursing educational methods and models of nurse-physician interaction in research settings.

In a descriptive study of oncology physicians' and nurses' attitudes of offering clinical trial results to study patients, Partridge, et al. (2004) identified oncology nurses and physicians through the Cancer and Leukemia Group B (CALGB) database [CALGB is a federally funded network to conduct cancer clinical trials]. Surveys were mailed to 1,977 members and 796 (40.3%) responded. Responders included 125 (15.7%) nurses, 650 (81.7%) physicians, and 21 (2.6%) individuals who identified themselves as "other" (psychologists, epidemiologists, etc). This study was primarily descriptive. Approximately 62% of respondents reported offering results to patients less than one-fifth of the time. Almost 79% of responders felt trial results should be offered to most study subjects. Patients want to know trial results according to 72.4% of respondents, and 62.2% of them did not believe that routinely offering results would have a negative impact on many patients. The study was limited by the use of a questionnaire that was not prospectively validated (Partridge, et al., 2004). Additionally, nonresponse rates differed among specialty groups. Fifty-two percent of nurses surveyed responded compared with

42% of medical subspecialists, 35% radiation oncologists, and 33% surgeons ($p<0.001$ for all four groups, $p = 0.0014$ for physicians only). The authors state that future studies should evaluate the process and effects of sharing results with study participants and they developed a model that includes the views of all parties involved. They feel this type of research may improve communication between health care providers and patients, and increase patient satisfaction with the care received during a clinical trial (Partridge et al., 2004).

In Greece researchers examined Greek nurses' attitudes toward truth-telling practices when working with cancer patients and their psychological status regarding the difficulties they faced in their day-to-day communication with these patients (Georgaki, Kalaidopoulou, Liarmakopoulos & Mystakidou, 2002). The researcher designed questionnaire had 19 questions, including both multi-item scales and single item measures. The response options were "yes," "sometimes," or "no." The questionnaire was mailed to head nurses in Athen's oncology hospitals and oncology departments of general hospitals. These nurses were asked to distribute it to their nurses. Two hundred staff nurses were asked to participate, 148 nurses (74%) completed and returned the questionnaire. The results revealed that 75.7% of respondents believed that only some cancer patients should be told the truth of their diagnosis and prognosis and a larger percentage (89.1%) believed that the truth should be told to relatives. Most respondents (66.2%) reported that it is difficult to engage in open communication with the patients, because their education did not provide sufficient training in communication skills. Eighty four percent reported that they do not reveal that the disease is incurable, 58.1% believed that only the patient's physician should reveal the truth. These results indicated

that although many Greek nurses believe that the patients should be informed and know their condition, lack of training in communication skills is a major obstacle to achieving this.

Chang (2004) conducted a review of the nursing literature of published works (CINAHL, MEDLINE, PsycInfo, EBM reviews) exploring nurses' perceptions of Phase I clinical trials in pediatric oncology. The author found no literature related to this topic, except for the one previously discussed by Burnett et al. (2001) that reported nurses' attitudes toward adult clinical trials.

Patient, Public, and Physician Attitudes and Perceptions

Attitudes of patients and the public were evaluated in a study conducted over 20 years ago by Cassileth, Lusk, Miller, and Hurwitz (1982). One hundred and four patients with cancer, 84 cardiology patients and a control group of 107 members of the general public completed an anonymous self-report questionnaire consisting of 10 multiple-choice questions and one open-ended item. Respondents' opinions on the purpose and ethicality of clinical research were obtained. Responses to the questionnaire items did not differ by each group (patients with cancer, cardiology patients, general public) nor by demographic variables such as age or sex. Therefore, data were reported on the total sample of 295 respondents. Seventy-one percent of respondents believed that patients should serve as research subjects and 52% of respondents stated the main reason they would participate in medical research would be to get the best medical care. Thirty-six percent of respondents felt patients received better care when the treatment plan is determined by their physician. Thirty-eight percent felt patients received better or equal care when their treatment is based on a research protocol. A large percentage of

respondents (70%) thought that physicians have prior knowledge of which one of the investigated treatments is best. Since a large percentage expressed this belief, it can be inferred that many people do not understand the nature of clinical trials. This is an area where oncology nurses can assist patients with the information and education regarding the purpose of clinical trials.

Patients' Attitudes

Ellis et al. (2001) conducted a cross sectional survey of women ($N = 545$) attending a breast clinic for screening mammography or diagnostic assessment plus women with newly diagnosed breast cancer, the purpose was to assess attitudes toward and willingness to participate in randomized clinical trials of breast cancer treatment. A questionnaire was developed using information obtained from focus group interviews in conjunction with a review of the literature. The questionnaire contained information from the following areas:

1. Demographic data, including age, marital status, education, occupation, ethnicity, and medical/allied health training.
2. The Hospital Anxiety and Depression Scale (HADS) a questionnaire that contains seven items assessing symptoms of anxiety and seven items assessing symptoms of depression (Moore et al., 1991; Zigmond & Snaith, 1983).
3. Women's preferences for the amount of information they wish to receive from their doctor using a three-item scale previously described by Cassileth, Zupkis, Sutton-Smith (1980) and their level of involvement in clinical decision-making using a five-item scale (Degner, et al., 1997; Degner & Sloan, 1992).

4. Knowledge about the need for clinical trials and about the manner in which randomized clinical trials are conducted, which was measured using a 7-item scale developed by the authors of the study.

5. Attitudes toward randomized clinical trials, which was measured using a 36-item scale developed from focus group data and a review of the literature that measured the impact of individual items on women's willingness to participate in randomized clinical trials on a seven-point Likert scale (7 = very likely to join a trial, 4 = would not influence my decision, 1 = very unlikely to join a trial).

6. General willingness to participate in randomized clinical trials.

7. Reasons to consider joining/not joining a clinical trial.

The findings suggested that women who have a better understanding of issues about clinical trials had more favorable attitudes toward clinical trials and were more willing to consider participation.

Daugherty et al. (1995) conducted a pilot survey study of the perceptions of cancer patients and their physicians involved in Phase I cancer trials. Thirty cancer patients who had given informed consent to participate in a Phase I clinical trial and eighteen oncologists were surveyed. Eighty-five percent of patients reported that they participated in a Phase I trial, because of possible therapeutic benefit. Ninety-three percent of patients said they understood all or most of the information provided about the trial; however, only 33% were able to state the purpose of the trial in which they were participating. The authors concluded that cancer patients who participate in Phase I trials are strongly motivated by the hope of therapeutic benefit. Cancer patients who participate in Phase I trials appeared to have an adequate knowledge of the risks of experimental

therapy. However, only a minority of patients appear to have an adequate understanding of the purpose of Phase I trials.

Comis, et al. (2003) conducted a study to understand the attitudes of American adults toward participation in cancer clinical trials. A national probability sample of 1,000 adults aged 18 or older living in noninstitutional settings were interviewed via telephone by Harris Interactive. The results indicated that the primary problem with accrual is not the attitudes of patients, but the loss of potential participants is the result of the unavailability of an appropriate clinical trial. The authors also state that many patients hold mistaken views of the nature of clinical trials, and that many significantly overestimate the efficacy of standard therapies in making their decisions.

In a study describing and comparing the perceptions of cancer patients and their physicians regarding Phase I clinical trials, Meropol et al. (2003) surveyed eligible patients who were offered Phase I trial participation, had accepted, but had not yet begun treatment (n = 328). Each patient's physician also was a study subject (n = 48). Patients and physicians completed questionnaires with domains including perceptions of potential benefit and harm from treatment (experimental and standard), relative value of quantity and quality and length of life, and perceived content of patient-physician consultations. Patients had high expectations regarding treatment outcomes (e.g., median 60% benefit from experimental therapy). Patients predicted a higher likelihood of both benefit and adverse reactions from treatment (experimental and standard) than their physicians ($p < 0.0001$ for all comparisons). Although 95% of patients reported that quality of life was at least important as length of life, only 28% reported that changes in quality of life with treatment were discussed with their physicians. In contrast, 73% of physicians reported

that this topic was discussed ($P < 0.0001$). The authors conclude that this discrepancy in reports of consultation content, particularly given patients' stated values regarding quality of life, raise the possibility that such communication is suboptimal.

There were other studies which suggest that patient understanding about clinical trials can be improved through the provision of greater amounts of information (Aaronson et al., 1996; Davis, Nealon, & Stone, 1993; Simes et al., 1986).

The study by Aaronson et al. (1996) is the only study which used a nursing intervention to evaluate improving the informed consent process. The authors evaluated a strategy of providing additional information to patients considering entry into Phase II or III trials at the Netherlands Cancer Institute ($N = 180$). Patients were randomized to the standard consent interview, or the standard interview followed by a telephone call several days later from a clinical trials nurse to further discuss the information provided in the consent interview. As compared with patients provided only with verbal and written information from their treating physician (control group), those who also received information from an oncology nurse (intervention group) were better informed about the potential side effects of the proposed treatment, the clinical trial context in which the treatment was to be given, and many of the essential details of the clinical trial. The largest gains were observed in the percentage of patients aware of randomization procedures and of the right to withdraw from the trial. Patients in the intervention group were slightly more likely to decline participation (24% vs. 13%). The authors conclude that this type of nursing intervention, as an adjunct to established informed consent procedures had a positive effect on cancer patients' awareness of the most salient issues that surround the Phase II and III clinical trials in which they are asked to participate.

While this trial occurred outside the U.S., this institution is an active member of the national clinical trials group in the U.S. The nursing intervention that was described was consistent with U.S nursing practices. This study represented a beginning attempt at formalizing a unique role of the nurse in the informed consent process, as focused on knowledge and education of patients.

Davis et al. (1993) randomized patients considering entry into Phase III clinical trials to receive either standard information about clinical trials or standard information plus a NCI booklet explaining clinical trials. Two hospitals tested the booklet with patients who were eligible for a specific clinical trial, and two hospitals tested the booklet with patients who were theoretically eligible for a clinical trial (with a cancer site and stage for which a trial existed). Patients were assigned randomly: 203 experimental subjects received the booklet, and 194 control subjects were not given the booklet until after completing a 2-week post-test examining attitudes, knowledge, and beliefs about clinical trials. Overall patients who received the booklet were more knowledgeable about clinical trials, but there were no differences in participation rates.

Simes et al. (1986) randomized patients eligible for entry into randomized chemotherapy trials to ether full or individualized information disclosure. Patients in the full disclosure group had significantly greater knowledge about their illness and treatment and about the research plan. There were no significant differences between groups, although patients in the full disclosure group were a slightly more likely to decline trial participation (18% vs. 7%).

D. Oncology Nurses Role

Oncology nursing practice is delineated by the ONS in "Statement on the Scope and Standards of Oncology Nursing Practice" (ONS, 2004). Oncology nursing encompasses the role of direct caregiver, educator, consultant, administrator, and investigator (ONS, 2004). Additionally, oncology nurses act as patient guides and advocates by "assisting patients and families to seek information, ensuring informed consent regarding treatment decisions, and promoting the maximal level of patient-desired independence" (ONS, 2004, p. 8). An ONS professional performance standard of relevant to this study is standard five, ethics, which states, "The oncology nurse uses ethical principles as a basis for decision making and patient advocacy" (ONS, 2004, p. 37).

Oncology Nurses' Role in Clinical Trials

Nurses have a critical role with informed consent. They help patients become more effective partners in the clinical trial decision-making process by explaining how scientific advances are made, describing the patients' roles and rights in the studies, and providing sources for more information (Sadler et al., 1999).

Patient advocacy includes assisting patients in defining their own goals and purposes for participating in a clinical trial (McEnvoy, Cannon, & MacDermott, 1991). Depending upon the practice setting, oncology nurses have responsibility for recruiting participants, explaining informed consent, monitoring participant responses, documenting data, and serving as a liaison with multidisciplinary teams (Liaschenko & DeBruin, 2003). This demonstrates the multifaceted role of oncology nurses in the conduct of clinical trials. The ONS (1998) position statement on cancer research and cancer clinical

trials states that "coordination of clinical trials (e.g., coordination of clinical sites, development of standardized treatment orders, symptom management, patient education and advocacy, facilitation of informed consent, assistance with participant accrual and retention) is best accomplished by RNs who have been educated and certified in oncology nursing" (p. 973). As clinicians, nurses are expected to be direct caregivers (Grady, 1991; McEvoy, Cannon, & MacDermott, 1991) and coordinators of care (Hazelton, 1991; McEvoy et al.), as well as educators and patient advocates (Bujorian, 1988; Grady; McEvoy et al.; Rosse & Krebs, 1999). As research nurses, they are expected to be facilitators, liaisons, (Engelking, 1992), and data collectors (Cassidy & MacFarlane, 1991 ;Grady).

Ocker and Plank (2000) reviewed the nursing literature, analyzed job descriptions of oncology nurses, and conversed with research staff, oncology staff, and a clinical nurse specialist within an oncology research program in a large outpatient oncology clinic. They identified three oncology nurse roles for involved with clinical trials: patient educator, patient advocate, and study coordinator. Nurses greatly effect prospective patients' perceptions of clinical research. They explain technical and complex protocols in understandable terms. As patient advocates, nurses have a critical role with the informed consent process. They ensure that patients are treated with respect, dignity, and as autonomous individuals (Barrett, 2002). Therefore, nurses are in an ideal position to provide patients with information about informed consent, to facilitate physician-patient communication and to serve as patient advocates (Winslow, 1984).

Berry, Dodd, Hinds, and Ferrell (1996) suggest that informed consent for oncology clinical trials is an ongoing process involving many steps. Establishing and

maintaining informed consent should be a multidisciplinary effort in cancer clinical trials. As patient educators and advocates, nurses have maximized patient understanding and minimized potential coercion.

The actual act of obtaining a signature on the consent form is the physician's legal responsibility, but nurses have a moral responsibility to ensure that patients have a good understanding of that to which they are consenting (Rosse & Krebs, 1999). To be effective in this role, nurses must be knowledgeable about fundamental concepts associated with informed consent (Rosse & Krebs, 1999). As noted above in the study of Meropol et al. (2003), the differences in perceptions of adult patients and their physicians regarding treatment outcome expectations may be due to suboptimal patient-physician communication discussions of clinical trial participation. Nurses can play a key role in assessing and minimizing this discrepancy.

Nurse-Patient Relationships

Husted and Husted (2001) wrote extensively about the nurse-patient relationship and stress the nurse-patient agreement. They developed a theory called Symphonology which states; "Every human relationship arises from an explicit or implicit agreement….The principles by which a professional makes a decision ought to be derived from the actual dynamics of this agreement" (p. 9). The nurse is the "agent of a patient doing for a patient what he would do for himself if he were able" (Husted & Husted, 2001, p. 36). Husted and Husted (2001) prefer the term "agency" to "advocacy." They define agency, "the power or capacity of an agent to initiate action" (Husted & Husted, 2001, p.285). A person's agency is "the power to act on autonomous desires that spring from his or her own reasoning" (Husted & Husted, 2001, p. 195). Part of a nurse's

role is to be an agent for his/her patient. The nurse agreed to protect the rights of the patient through the implicit agreement between them. This implicit agreement forms the basis of the oncology nurses' role in discussing clinical trials with patients. As explained in section D, the role of the oncology nurse consists of educator, consultant, and patient advocate, or agent as Husted and Husted (2001) posit. The oncology nursing role as educator and agent of clinical trials patients are all part of the nurse-patient relationship. The nurse-patient relationship comprises the foundation for communication between nurse and patient. During the communication process, as agents for their patients, nurses provide clarification of information that a patient may not understand. This is especially important with regard to informed consent required for oncology patients and clinical trial participation. The nurse-patient relationship as stated by Husted and Husted enable oncology nurses to help patients become more effective partners in the clinical trial decision-making process.

E. Summary of the Review of Literature

The role of beliefs, attitudes and perceptions in the decision-making process and in predicting behavior forms the foundation for this study. The TRA proposes that attitudes guide behavior. It is a theoretical framework that was used in other nursing studies evaluating attitudes and perceptions. Additionally, if behavior were expected to be based on specific beliefs and attitudes, then measuring those beliefs and attitudes is a way of predicting behavior (Sanbonmatsu & Fazio, 1990).

One way to begin to assess the actions of the oncology nurse towards patients contemplating or participating in clinical research is to investigate their attitudes and perceptions. Hence, the nurse's perceptions and consequent attitudes regarding cancer

clinical trials may ultimately dictate their behavior towards patients enrolled in or contemplating enrollment into a cancer clinical trial. Within the practice of oncology nursing, these behaviors can include direct patient care, coordination of care, patient education, and patient advocacy.

Oncology nurses have a pivotal role when caring for patients considering participation in a clinical trial. Nurses provide education to patients and clarify information. This fact is underscored by the study by Aaronson et al. (1996). They utilized a nursing intervention which demonstrated a positive effect on cancer patients' awareness of the most important issues surrounding clinical trials participation.

Additionally, nurses serve as patient educators and assist patients in the decision-making process. Nurses perceive their role differently from that of other healthcare professionals in that, they concentrate on patient advocacy and caring (Krisjansdottir, 1992). This caring focus enables nurses to ensure adequate communication with patients about treatment regimens. Nurses may be more aware of patients' attitudes towards research due to this type of patient-nurse relationship. Nurses' attitudes and perceptions may influence patient's opinions regarding participation and may reflect patients concerns in this area. The nursing role and caring focus outlined above are all part of the nurse-patient relationship. Within the nurse-patient relationship, specific to oncology nursing, the nurse's role consists of educator, counselor, patient advocate, direct caregiver and investigator. Exploring oncology nurses' attitudes and perceptions toward clinical trials may help to predict the behaviors required to function optimally in these roles.

Studies show that patients often do not understand the purpose of clinical trials and may have unrealistic expectations regarding their benefits (Cassileth, Lusk, Miller, & Hurwitz, 1982; Daugherty et al, 1995). Nurses have an integral role in the informed consent process. Further exploration of oncology nurses attitudes toward clinical trials and their perceptions of patient understanding is needed.

The oncology nurse has an important role in all aspects of clinical trials and the care of patients enrolled or contemplating enrollment. However, it is unfortunate that there is very little information concerning nurses' attitudes and perceptions regarding cancer clinical trials. Only one study concerning oncology nurses' attitudes towards cancer clinical trials in a comprehensive cancer center exists (Burnett et al., 2001). These data revealed that the majority of nurses feel that cancer clinical trials advance standards of cancer treatment. However, approximately half would recommend their patients for a clinical trial, most would not participate in a clinical trial if they had cancer. There appears to be a discrepancy between what these oncology nurses feel about clinical trials and what they would actually do. The authors' recommendations for future research were the to replicate their study with other comprehensive cancer center nurses; to conduct a study with nurses from settings other than a comprehensive cancer center, and to compare the findings between these different groups, and to study current nursing educational methods and models of nurse-physician interaction in research settings. This study is an attempt to examine the attitudes and perceptions of a more heterogeneous group of oncology nurses.

CHAPTER III: METHODS

The chapter explains the study design. Followed by a description of the sample, including sample size and the setting in which the data were collected. The information about the instruments used is in the next section. Finally, procedures for data collection, the protection of human subjects and the data analysis plan are the last three sections.

A. Design

This study was a descriptive, nonexperimental study of a sample of practicing oncology nurses that explored oncology nurses' attitudes and perceptions toward clinical trial participation. The study further sought to understand factors that oncology nurses believe influence patients' decisions to participate in cancer clinical trials, and to learn which nurses' characteristics are predictive of positive attitudes towards cancer clinical trials and perception of patient understanding.

A survey method was employed. The purpose of a survey design is to generalize from a sample to a population, so inferences can be made about some characteristic, attitude, or behavior of this population (Babbie, 1990). As noted in the review of the literature, little is known about nurses' attitudes and perceptions towards cancer clinical trials. Most literature evaluating attitudes and perceptions towards clinical trials has concentrated on patients, the community, and physicians, rather than on nurses. The investigator used mailed survey instruments. There are a number of advantages of mailed surveys. They allow for wide geographic coverage as compared with surveys administered in person. Another advantage of a mailed survey is

in the timing of the data collection. The assumption with a mailed survey is all the members of the sample receive it nearly simultaneously. Therefore, the potential influence on respondents' experiences, opinions, or attitudes that might come from events outside of or unrelated to the study is reduced and can be assumed to be equal for all recipients of the questionnaire (Bourque & Fielder, 2003).

One of the greatest and most studied disadvantages of using mailed surveys is their low response rate (Bourque & Fielder, 2003). According to Krosnick (1999), the common thought when conducting a survey is to strive for a 70% response rate. He noted response rates on national surveys have fallen in the last four decades. Krosnick challenged the thought that high response rates correlate with a high degree of representativeness of the sample and cited results in relation to national studies of voters. When probability sampling was done, there was no longer a need to associate low response rates with low representativeness (Krosnick, 1999). Research shows that a second mailing approximately three weeks after the first mailing is more effective than any other technique for increasing response (Dillman, 2000; Schaefer & Dillman, 1998).

Response rates reported from past mailed surveys sent to Oncology Nursing Society (ONS) members ranged as follows: 23% (Jerewski, Brown, Wu, Meeker, Feng, & Bu, 2005); 24% (Taylor, Highfield, & Amenta, 1994); 25% (Volker, 2001); 26% (Rutledge & Engelking, 1994); 30% (Bavier, 2003); and 37.7% (Sarna, Wewers, Brown, Lillington, & Brecht, 2001). The study by Jerewski, et al. (2005) used a stratified, random sampling approach and asked questions regarding knowledge, attitudes, and experiences about advanced directives analyzed with descriptive statistics and regression analysis. Taylor et al.'s (1994) study also used a stratified random sampling approach asking

questions about spiritual care analyzed using content analysis and descriptive statistics. Volker (2001) used a sequential mailing technique to gather stories of nurses in relation to requests for assisted dying. Rutledge and Engelking (1994) conducted a survey of randomly selected oncology nurses to describe their experiences with cancer related diarrhea, including occurrence and management. Bavier (2003) used a stratified random sampling approach in describing types of disclosure discussions between oncology nurses and patients/family members. Sarna et al. (2001) conducted a survey of randomly selected members of ONS about tobacco control and barriers and facilitators to delivering tobacco cessation interventions to patients. The authors do not state specific strategies used to maximize response to their surveys. Sarna et al. (2003) stated that a reminder postcard was sent to encourage return of the questionnaire but, when the postcard was sent was not reported. However, three to four weeks after the first mailing (N = 5,000), Rutledge and Engelking (1994) mailed another survey packet to nonrespondents. A total of 1,288 nurses (26%) responded, 600 to the first survey and 688 to the follow-up. It is encouraging to note that upon follow-up mailing Rutledge and Engelking (1994) yielded a greater number of respondents compared to the first mailing. This study planned on utilizing the same technique as Rutledge and Engelking (1994) to send a follow-up mailing to nonrespondents in case the minimum sample size was not obtained with the first mailing; however, a second mailing was not necessary (see Sample Size and Procedures for Data Collection sections).

B. Sample and Settings

In this study, a proportional stratified random sample of the membership of the ONS was used to make inferences between oncology nurses characteristics and their attitudes towards cancer clinical trials, their perception of patients' knowledge of the treatment plan and information needed related to clinical trials. In a proportional, stratified random sample, the population is separated into groups based on their proportions represented in the general population. Then, a random selection is drawn from each group with the proportion from each stratum being the same as the overall population. The stratified random sampling technique is an attempt at sharpening the representativeness of the final sample (Polit & Beck, 2004).

Sample Size

To assess instrument and subscales validity, the investigator performed a factor analysis of the data prior to the primary analysis evaluating the research questions (this will be explained fully in the data analysis section of this chapter). Factor analysis requires a minimum number of subjects per item for the instrument being utilized. Gorush (1983) and Hatcher (1994) recommend a minimum subject per item ratio of at least 5:1. The consensus among three authors is (Gorush, 1983; Hathcer, 1994; Nunnally & Bernstein, 1994) the number of subjects per item should be 5:1 to 10:1. Other authors have reported that there may not be one ratio that will work in all cases and a rule of thumb is an N>100 and that most factor analytic studies use N>200 (MacCallum, Widaman, Preacher, & Hong, 2001).

For this study the investigator utilized a 26-item instrument (see appendix A and instrument section of this Chapter) and the investigator followed a 5:1 to 10:1 ratio of

subjects per item; therefore, the minimum number of subjects needed for this study was130. However, after consulting a statistician with over 20 years experience in designing surveys, it was decided that a sample size of 230 subjects would be better (B. Pearman, personal communication, April 24, 2006). It has been shown that larger samples (i.e., >200 subjects) are better than smaller samples, because larger samples tend to minimize the probability of errors, maximize the accuracy of population estimates, and increase the generalizability of the results (B. Pearman, personal communication, April 24, 2006; Gorush, 1983; MacCallum et al., 2001).

Sample

A sample of registered nurse (RN) members of ONS who reside in the United States (US) and permit ONS to release their addresses was utilized. The total ONS nurse and non-nurse membership is approximately 32,000, approximately 23,000 members allow their names to be sold to outside organizations (ONS, 2006). There are approximately 16,150 nurse members who self-report their primary functional area as patient care or research with adults, excluding nurses who self-report their primary position as researcher/principal investigator.

One thousand labels of names and addresses were purchased from ONS for nurses who reside in the U S and who self-report patient care or research with adults as their primary functional area, and are employed full, or part-time, . The investigator requested that the list excludes nurses who reported that their primary position as researcher/principal investigator. There may be nurses who identify their primary functional area as “research” but in fact are clinical trials nurses and the investigator wanted to include them. Additionally, the investigator was interested in exploring the

attitudes and perceptions from oncology nurses who have direct patient care and whose primary position includes, but is not limited to, staff nurse, clinical nurse specialist, nurse practitioner, clinical trials nurse, and patient educator. This sample represents the majority of the population of nurses who care for oncology patients and is an attempt to improve the generalizability of the study.

The investigator requested ONS to stratify the 1,000 names by two variables: 1) primary work setting (e.g., in-patient hospital unit, outpatient facility or clinic, public health or visiting nurse service, hospice, etc.); and 2) highest degree attained (e.g., diploma, associate's, bachelor's, masters, doctorate). A random sample within each category was selected in proportion to the size of the group in that category. This group was a representative sample of the study population with the above proportional categories. The study packet was mailed to all 1,000 selected members. A cover letter (see Appendix B) was included in the mailing. This over sampling was required due to previously reported response rates between 24-37% to ONS mailed surveys.

C. Instruments

The nurses were asked to complete two instruments, the modified Nurses' Attitude Survey (NAS) (Appendix A), and a Demographic Information Form (see Appendix C).

Nurses Attitude Survey

The original NAS was survey tool developed by Meropol and colleagues (Burnett et al., 2001) that addresses nurses' attitudes toward cancer clinical trials and their perceptions about patients' reasons for participating as research subjects. The instrument was used only once at Roswell Park Cancer Institute (RPCI). RPCI is a freestanding

National Cancer Institute (NCI)-designated comprehensive cancer center. Between October 1996 and February 1997, 417 RNs employed at RPCI were surveyed. Nurses at RPCI care for a wide variety of patients in a array of settings, including outpatient and inpatient units, intensive care units (ICUs)/bone marrow transplant (BMT) units, and clinical research services. Two hundred-fifty (60%) of the 417 nurses responded. Ninety percent of the sample was female; 88% was white; the mean age of subjects was 42 years; and 47% of subjects were educated at the bachelor's or master's level. Practice setting was distributed fairly evenly across inpatient facilities, outpatient clinics, and ICUs and BMT units. Twenty-seven (11%) subjects identified themselves specifically as research nurses. Approximately one third of the total respondents (n = 82) reported caring for at least 50 patients annually on clinical trials.

The original NAS consists of a total of 59 consecutively numbered items including demographic information questions. The tool is divided into four sections: Section 1 (Clinical Research Using Patients as Research Subjects) consists of 15 items plus space for comments; Section 2 (Patient Care and Patient Communication) consists of 11 items and a space for comments; Section 3 (Nurses' Role in a Cancer Institute) is comprised of 16 items plus space for comments. To answer items in Sections 1 through 3, the participant chooses responses from a 5-point Likert scale (1 = strongly disagree, 2 = somewhat disagree, 3 = neither, 4 = somewhat agree, and 5 = strongly agree). Section 4 (About You) consists of 17 demographic questions.

Modification of the NAS. With permission from the authors (see Appendix D), the investigator modified the instrument for this study. This modification was requested

because certain items from the original instrument would obtain information that was outside the purpose of this study and only germane to the original study.

The 15 items contained in Section 3 were statements that address issues related to the nurses' employment, such as job satisfaction and support at work. Section 3 was deleted, because the information is outside the scope of this research. All demographic questions were included on a separate form (see Appendix C). Sections 1 and 2 of the NAS were modified and consisted of the 26 consecutively numbered items included in the original instrument (see Table 1).

Table 1

Modification of NAS

NAS section	Original NAS items	Modified NAS items
1. Clinical research using patients as research subjects	1–15	1–15
2. Patient care and patient communication	16–26	16–26
3. Nurses' role in a cancer institute	27–42	Deleted
4. About you	43–59	Demographic information to be captured on a separate form

Within the original instrument, the authors derived two subscales consisting of six items each. The authors used subscale one (Items 1, 5, 6 7, 8 and 11) to report nurses' attitudes toward patient participation in clinical trials and, subscale two (Items 12, 13, 18, 20, and 21) to report nurses' perceptions about factors related to patient care issues (e.g., respect, understanding of the treatment regimen, and informational needs). Cronbach's

alphas were reported for the two subscales as 0.78 and 0.63, respectively (Burnett et al., 2001). A Cronbach's alpha of 0.63 is lower than the widely-accepted social science minimum of 0.70. Usually an alpha level 0.70 and above is acceptable; however, it is a common misconception that if the alpha is low, it must be a poor test. Actually, the test may measure several attributes or dimensions rather than one and, thus, the Cronbach's alpha is deflated (Santos, 1999).

The authors of the NAS analyzed their data using the two subscales as outlined. Upon review of the instrument, the investigator found other items that could be grouped together to answer the research questions of this study and utilize all items in Sections 1 and 2 (see Table 2). However, the grouping of items in table 2 was proposed before the factor analysis was executed. After the factor analysis, the investigator found that some of the proposed items grouped with each other, while others did not (see chapter 4, Results). The authors of the NAS report that they established face and content validity for the instrument by an extensive review of the literature and a review of the instrument by three medical oncologists and two oncology nurses (Burnett, et al., 2001). Therefore, it was prudent that the investigator psychometrically evaluate construct validity of the modified NAS to assess that the dimensions (attitudes and perceptions) are being measured by the instrument subscales (Waltz, Strickland, & Lenz, 1991). Factor analysis was employed to justify these dimensions (see Psychometric analysis section chapter 4).

Table 2

Modification of the NAS Subscales to Match Research Questions

Research questions	Modified NAS subscale items	Original NAS subscale items
1. What are oncology nurses' attitudes toward the benefits of cancer clinical trials?	5. Clinical research improves patient care for the patient involved. 6. Hospitals that conduct clinical research have better standards of care than hospitals that do not. 7. Clinical research in oncology is important in improving standards of care in oncology. 8. Patients should be encouraged to participate in research. 11. If I had cancer, I would prefer to be treated as part of a clinical trial.	1, 5, 6, 7, 8, & 11
2. What are nurses attitudes about how effective a research drug or experimental therapy should be shown to be before it is offered to patients?	15. In your opinion, in order for a research drug or experimental therapy to be offered to patients, it should have at least a _____% chance of producing a desired effect (please insert a number)	Reported as frequency and distribution table by original authors
3. What are the nurses' perceptions regarding patients' understanding of clinical trials and treatment regimen	12. In general, patients are well informed when they choose to participate in a clinical trial. 13. Patients are often unaware that their treatment is part of a research protocol. 16. Patients' wishes regarding treatment are respected by nurses 19. Patients understand their prognosis and therapy goals. 20. Patients' prognoses are usually well explained. 21. Patients want to be informed.	12, 13, 18, 19, 20, & 21.

Table 2 *(continued)*

4. What factors do nurses perceive to influence a patient's decision to participate in a cancer clinical trial?	14. Patients participate in research because: A. Wish for cure B. Wish for improved quality of life (i.e., symptom control) C. Hope for better medical care D. Desire to please their oncologist E. Pressure from oncologist F. Wish to help others G. No other option H. Family wishes I. Inability to accept that nothing else can be done J. Inability to accept death	Reported as a frequency distribution table by original authors
5. What are nurses' perceptions of patients' decision-making processes and the desire for information regarding clinical trial participation?	22. When being told about their therapy, most patients pay more attention to potential benefits of therapy than side effects. 23. Most patients are willing to accept side effects for even a small benefit if therapy. 24. Patients are often frightened to ask questions. 25. Patients' decisions whether to accept or not accept toxic chemotherapy is strongly influenced by their family preferences.	N/A
6. What are the perceptions of nurses regarding where clinical research should be conducted and the role of oncologists and nurses in clinical trials?	1. Conducting research is an important role of oncologists. 2. Clinical research should be conducted only in cancer centers/institutes. 3. It is appropriate for oncologists to invite their clinic patients to be subjects in trials that they conduct.	N/A

Table 2 *(continued)*

	4. It is appropriate for oncologists to be the person consenting research subjects for their trials, if the research subjects are their own clinic patients 9. Oncologists put too much pressure on patients to participate in clinical trials 10. Nurses put too much pressure on patients to participate in clinical trials 17. Patients' wishes regarding treatment are respected by oncologists 18. Patients understand their plan of care/treatment. 26. Oncologists believe that patients are willing to accept side effects for even a small benefit of therapy.	
7. Do the demographic variables of age, education level, number of years in oncology, position of oncology nurses, and practice setting serve as significant predictors to attitudes and perceptions?	Were analyzed by regression equations based upon the responses to the above items.	Predictors reported by original authors.

Eight practicing masters prepared oncology nurses completed the modified instrument, as part of a field test of the instrument package and to provide feedback on the items. These nurses were not part of the primary study. Each nurse took fewer than10 minutes to complete the instrument. They all felt that the instrument asked for their opinion regarding cancer clinical trials, including information specifically about patients who participate in these trials. In the unmodified instrument Item 1 states "Conducting

patient research is an important role of oncologists" and Item 9 states "Doctors put too much pressure on patients to participate in clinical trials." The nurses recommended using similar language throughout the instrument. Therefore, wherever an item addressed doctor it was changed to "oncologist."

Demographic Information Form

The Demographic Information Form (DIF) was designed by the investigator using some of the demographic items contained on the original NAS and on the 2006 ONS membership application/renewal form. The DIF contained 10 items; six items were from a list of choices and four responses were open-ended requiring subjects to fill in a blank. One purpose of the DIF was to assist with the analysis of the sample characteristics in relation to the overall membership of ONS. Questions one, three, four, seven, nine, and 10 from the DIF were used in the evaluation of research question number seven that explored demographic variables (age, highest education level, whether or not the nurse actually works with patients contemplating enrollment or currently enrolled in a clinical trial, number of years in oncology, primary work setting, and primary position of oncology nurses) and evaluated if they served as significant predictors related research questions one through six (see Table 3). The remaining four questions on the DIF were used to further describe the sample (gender, current certification in oncology nursing, number of years as an RN, and percentage of patients offered cancer clinical trials where the subject worked). The questions were based on the independent variables of interest (see Table 3) and some mirror the items on the ONS membership application.

Table 3

Independent Variables from DIF

Independent variables (demographic categories) addressed in research question 7	DIF question
Age	1
Highest education.	3
Working with patients contemplating enrollment or enrolled in clinical trials.	4
Number of years in cancer nursing.	7
Primary work setting.	9
Primary position.	10

D. Procedures for Data Collection

The investigator obtained three duplicate sets of mailing labels from ONS, for a total sample of 1,000 members. This over-sampling was used with the goal of a 20-25% response rate in an attempt to yield 230 usable responses. All 1,000 names from the first set were mailed the study packet. The only identification was a numeric code on the return envelopes and corresponding numerical codes on the second and third mailing labels. When a subject returned the survey, his/her name was removed from the second and third sets of mailing labels and the envelopes shredded. The code did not appear on any of the instruments or cover letter. This was to ensure that names were not connected with answers in any way and to provide anonymity to the respondents. If there were fewer than 230 usable surveys 3 weeks after the first mailing, the investigator planned on

mailing a second survey packet with the instruments and a new cover letter (Appendix E) to all remaining names (Dillman, 2000). This was not necessary, because the investigator had received more than 230 usable surveys 3 weeks after the mailing (see chapter 4, Results). At the end of the study, the investigator destroyed all codes and remaining address labels.

Additionally, the cover letter (see Appendix B) stated the inclusion criteria for this study as follows: (a) nurses whose primary functional area is patient care or research with adult patients, and (b) any primary position other than researcher/principal investigator. There was a box on the cover letter for the subject to check if they do not meet these criteria with instructions to return the cover letter in the supplied stamped addressed envelope.

After obtaining approval from the Institutional Review Board (IRB) of Duquesne University, survey packets were mailed (Appendix F). The packets contained: (a) an IRB approved cover letter (Appendix B), (b) the modified NAS (Appendix A), (c) the DIF (Appendix C), (d) and a stamped return envelope addressed to the investigator.

E. Procedures for the Protection of Human Subjects

The investigator requested approval for conducting the study from the IRB of Duquesne University, utilizing standard forms and procedures set forth by the committee. The investigator provided an overview of the research questions, design, methods, and a sample packet of data collection tools. The IRB approved the study on May 24, 2006. The investigator received a letter from the chair of the Duquesne University IRB, Dr. Paul Richer (Appendix F) stating that the study received expedited

approval as well as an IRB approved cover letter to be used in the survey packet (see Appendix B).

Participation in the proposed study was voluntary, and all subjects had the right to refuse. Potential subjects were informed that results would be reported in an aggregated format, with no information identifying any individual. The only identification was a numeric code on the return envelopes and a corresponding numerical code on the second and third set of mailing labels. As mentioned above, when a subject returned a survey the person's name was removed from the mailing list and the envelopes shredded. The code did not appear on any of the instruments or cover letter. At the end of the study, all codes and remaining address labels were destroyed by the investigator.

During the study the investigator, kept all of the returned instruments and address labels in a locked file cabinet separate from any data. The completion of the survey instrument and the mailing of the instrument to the investigator were considered to be consent by the individual to participate in the proposed study. The cover letter provided a means for individuals who had concerns about the study and wished to discuss issues a way to contact the investigator (Appendix B).

F. Data Analysis Plan

Data analysis occurred in two steps. In step one, the investigator psychometrically evaluated the survey instrument by completing a factor analysis of the data to confirm the validity of the grouped items with this population of oncology nurses and assessed reliability of the instrument and the subscales. Data were analyzed statistically using SPSS® (version 11.5) (SPSS Inc., Chicago, IL).

Upon receipt of each completed survey, a research assistant entered the data onto a spreadsheet (Excel by Microsoft®, Redmond, WA) created by the study statistician. For quality control the investigator rechecked all data entered for each subject. The data were then exported to SPSS® for data analysis.

As noted in the review of the literature in chapter 2, the NAS was used in one pilot study of oncology nurses in a comprehensive cancer center (Burnett et al., 2001), and the investigator could not find any other instruments that have been created to measure nurses' attitudes and perceptions regarding cancer clinical trials. As stated, the authors of the original instrument analyzed data using two subscales consisting of six items each, which are embedded within the entire NAS. The authors used Subscale 1 to measure nurses' attitudes toward patient participation in clinical trials, and Subscale 2 to measure nurses' perceptions about factors related to patient care issues (e.g., respect, understanding of the treatment regimen, and informational needs). In addition to the 12 grouped items which make up Subscale 1 and 2 (six items for each subscale), the remaining items on the NAS were grouped together to address the research questions for this study. Therefore, all of the research questions were evaluated by four subscales and two individual items, which contained all the 26 items of the NAS. This will be explained fully in the analysis of variables section of this chapter.

In establishing six groupings of items to address six research questions, validity and reliability of the NAS was evaluated prior to addressing the research questions posed by this study. Psychometric evaluation of the NAS was accomplished by factor and reliability analysis. Factor analysis addresses the validity of a scale or subscale by evaluating the extent to which the abstract constructs purported to be measured, can be

inferred from the factors or subscales (Waltz et al., 1991). Reliability measures the internal consistency and reliability of a scale or subscale and was evaluated by calculating Cronbach's alpha (Polit & Beck, 2004).

Factor Analysis

Factor analysis of the NAS was performed first to determine if the proposed items and subscale items grouped together. Factor analysis is a generic term for a family of statistical techniques concerned with the reduction of a set of observable variables in terms of a small number of latent factors or constructs (Hutcheson & Sofroniou, 1999). Factor analysis was developed primarily for analyzing relationships among measurable entities, such as survey items or test scores (Gorsuch, 1983). The underlying assumption is there exists a number of unobserved latent variables (or "factors") accounting for the correlations among observed variables, such that if the latent variables are partialled out or held constant, the partial correlations among observed variables all become zero (Morrison, 1990). In other words, the latent factors determine the values of the observed variables. The main applications of factor analytic techniques are (a) to reduce the number of variables and (b) to detect structure in the relationships between variables that classify similar variables together (Hutcheson & Sofroniou, 1999).

The factors, then, are groups of variables measuring a common construct or factor. In a principal components factor analysis, all sources of variability (unique, shared, and error) are analyzed for each variable. In factor analysis, only shared variability is analyzed (Gorsuch, 1983). This is based on the assumption error and unique variance which only serve to confuse the underlying structure of the variables. In this study, a principal components factor analysis was utilized. This study also utilized an

orthogonal or varimax rotation (Gorsuch, 1983). This rotation results in identifying factors that are uncorrelated with each other. The factor loadings or the matrix of correlations between all observed variables and factors was inspected, since the size of the loading is indicative of the relationship between each observed factor and variable. The interpretation of factors or analysis always involves a certain amount of subjectivity. In order to be effective and avoid potential bias, the minimum factor loading was set at 0.30 (Gorsuch, 1983; Waltz & Bausell, 1981). Items or variables loading below 0.29 were considered for elimination from the scale. It also was anticipated that items would load on one, and only one, factor (Gorsuch, 1983). This was accomplished before any further analyses of data, so that the grouped items could be evaluated and altered if necessary.

It was anticipated that most of the proposed subscale items would factor together (Betsy Pearman, personal communication, April 24, 2006). However, the factor analysis revealed that some of the proposed item groupings (Table 2) factored together, while some items factored with others. The investigator planned on two strategies to address factor loading of an item or items below 0.30: (a) If new factor arrangements (subscales) were identified and provided useful information and evaluated the underlying constructs (attitudes and perceptions), then the investigator would utilize the new arranged factors to analyze the data; (b) if the constructs were not identified within a new factored arrangement then the investigator would evaluate reliability of the new factored arraignment and compare it to the reliability of the proposed subscales. The more reliable arrangement would then be used for the data analysis. The investigator found that some

items of the proposed subscales (Table 2) factored together, while other items factored in with different items (See chapter 4, Psychometric analysis section).

Reliability

Reliability of the NAS and the subscales of grouped items were measured with a Cronbach's alpha. Cronbach's alpha is a coefficient of reliability (or consistency) and is the most common estimate of internal consistency of items in a scale (Cronbach, 1951). Cronbach's alpha measures how consistently a set of items is measured. In other words, upon repeated testing of a scale or subscale, the same results are obtained, and to what extent the item responses obtained at the same time correlate with each other (DeVellis, 2003). Three factors that can affect the size of an alpha coefficient include the number if items on the subscale, the ability of the person completing the items, and the method of computing reliability (Polit & Beck, 2004).

Analysis of Research Questions

Research Questions 1, 2, 3, 5, and 6 were analyzed by evaluating the mean scores obtained from the survey items (summed subscale scores for Questions 1, 3, 5, and 6 and mean percent for question 2) with $p = 0.05$ as the level of significance (see chapter 4 for results). Research Question 4 was analyzed using descriptive statistics and frequencies of Item 14 were reported.

Stepwise multiple regression was used to analyze research Question 7. For this analysis, regression was used to test the effects of six independent (predictor) variables (age, education level, number of years in oncology, whether nurses care for clinical trial patients or not, position of oncology nurses, and practice setting) on the dependent (criterion) variables, attitudes and perception, as measured by the NAS subscales.

Regression analysis measures the degree of influence of the independent variables on the dependent variables (Stevens, 2002). Multiple regression can establish that a set of independent variables explains a proportion of the variance in a dependent variable at a significant level (through a significance test of R^2), and can establish the relative predictive importance of the independent variables (Brace, Kemp, & Snelgar, 2006). The adjusted R^2 takes into account the number of variables in the model and the number of participants on which the model was based. The adjusted R^2 value gives the most useful measure of the success of the model. However, there may be very little difference between the R^2 and adjusted $R^{2,}$ and some authors recommend checking for differences between the two and reporting only the R^2 (Brace et al.; Stevens, 2002,). An R^2 close to 1.0 indicates that almost all the variability with the variables specified in the model have been identified. Therefore, a R^2 close to 1.0 is desirable because it indicates that the predictor variables are a good predictor of the criterion (dependent variables). Conversely, a low R^2 indicates the predictor variables account for little variance and there is variance in the model that is accounted for from an unknown source. When a regression model has a low R^2 there may be some other factor accounting for the variance. As an example, if the R^2 is 0.12, then only 12% of the variance is accounted for, and there is an unknown variable that will affect future results, if that regression model were being used to predict group scores on a subscale. It would be difficult to use the predictor variables to predict the scores on the subscale if the regression model is only accounting for 12% of the variance (Tabachnick & Fidell, 2001).

Another important result from a multiple regression analysis is the standardized regression coefficient, beta (ß). The beta regression coefficient is a measure of how

strongly each predicator variable influences the dependent or criterion variable. The higher the beta value, the greater the impact of the predictor variable on the dependent variable (Brace, et al., 2006). Five stepwise multiple regression models were constructed to explore further the relationship of the independent variables and the outcome variables of attitudes and perceptions.

As a general data analysis approach, bivariate comparisons of mean scores were performed using one-way analysis of variance (ANOVA) tests with age, educational level, whether the nurse works with a patient enrolled on or contemplating enrollment in a clinical trial, years in cancer nursing, primary work setting, and primary position as independent variables and the scores of the subscales as the dependent variables. When significant differences in mean scores were found within an independent variable a post-hoc multiple comparison test then was performed.

For independent variables where there were more than two groups, the data were further analyzed with a Bonferroni post-hoc multiple comparison test. The Bonferroni adjustment is a statistical adjustment for multiple comparisons (Seaman, Levin, & Serlin, 1991). The Bonferroni post-hoc test uses t tests to perform pairwise comparisons between group means, but controls overall error rate by setting the error rate for each test to the level of significance (alpha level) divided by the total number of tests (Keppel & Wickens, 2002). Hence, the observed significance level is adjusted for the fact that multiple comparisons are done.

The Bonferroni post-hoc test calculates an adjustment as a way of control when multiple tests of the data are analyzed, and accounts for testing the same population many times (Keppel & Wickens, 2002). For example, if five groups are being tested in a

pairwise fashion, there are10 possible combinations of pairwise comparisons. The alpha level of significance for this study was set at $p = 0.05$. With the Bonferroni adjustment the alpha level is divided by the number of pairwise comparisons. For 10 pairwise comparisons, the level of significance now becomes $p = 0.005$. This ensures that the overall chance of making a Type I error is still less than 0.05.

Independent Variable Groupings

Age. The independent variables were placed into groups for data analysis. The sample was divided into two groups to evaluate age: Group 1 represents nurses' less than or equal to 40 years old and Group 2 represents nurses greater than 40 years old. The cut point of 40 years of age was chosen for several reasons. Burnett, et al. (2001), found age greater than 40 years was a predictor of positive attitudes towards clinical research. Additionally, the investigators found that 236 (78.4%) nurses were 40 years or older with a mean age of 48. Both the sample and the ONS membership reflected the general nursing population with the majority over the age of 40 (Buerhaus, 2002). Moreover, 66% of ONS members are over the age of 40 (Kristina Gantner, Personal Communication, July 19, 2006).

Educational level. To evaluate the independent variable of educational level it was classified into three different groups. Group 1 included nurses who had a diploma in nursing or an associate degree in nursing or any other field. Group 2 included subjects with a bachelor's degree in nursing or any other field. The third group included subjects with a master's degree or higher in nursing or any other field. These groupings were chosen to see if there were differences in the responses of subjects with bachelor's degrees compared to subjects with lower or higher educational degrees.

Working with clinical trial patients. Question number four on the DIF asked subjects if they work with, or care for, patients contemplating enrollment in, or currently enrolled in, cancer clinical trials. The subjects responded either yes or no. For the data analysis the subjects were divided into two groups, Group 0 = no and Group 1 = yes.

Number of years in cancer nursing. To evaluate for differences in responses, the number of years a subject worked as an oncology nurse was divided into three groups. Group 1 were subjects who indicated less than ten years experience, Group 2, 11–20 years experience, and Group 3 greater than 20 years experience. The investigator decided upon three groups based upon the average number of years falling between 10–20 years. He felt that a group with less experience and a group with more experience than the average were warranted to provide meaningful comparisons.

Primary work setting. For primary work setting there were three main groups of subjects, inpatient setting, outpatient setting, and other. These groups were further separated into six different work settings. Group 1 consisted of bone marrow transplant unit/intensive care unit (BMTU/ICU) nurses; Group 2 consisted of nurses working on a medical surgical inpatient oncology unit and an inpatient oncology specialty unit (MSOU). The Group 3 consisted of nurses who stated they work at a hospital based infusion center (HBIC). Group 4 consisted of nurses who reported they work in a physicians' office (MDO); Group 5 reported they work in a corporate or industry setting (CI), and Group 6 were nurses who reported "other" (OTHER). These groups represent the majority of nurses working in oncology and in the ONS membership (Kristina Gantner, personal communication, July 19, 2006).

The investigator decided to include Group 5, corporate/industry practice setting, in the data analysis for several reasons. This variable is identical to a choice on the 2006 ONS membership application. The cover letter informed subjects that they were selected to receive the survey based upon a random sample of nurses who self-report their primary functional area as patient care or research with adults, excluding those who self report researchers/principal investigators as their primary position (inclusion criteria). The cover letter gave the subjects the opportunity to check a box and return the letter if they did not meet these inclusion criteria. Lastly, it was impossible to differentiate between nurses who work in corporations and provide patient care, those who work in research organizations providing clinical trial support, and those who work in the pharmaceutical industry.

Primary position. The variable, primary position was divided into four groups for the analysis. This information was taken from the responses to question 10 on the DIF, which asked subjects to indicate their primary position. This question is identical to an item on the ONS membership application, asking for the same information. Group 1 included nurses who indicated they were staff nurses; Group 2 included subjects who indicated they were clinical nurse specialists or nurse practitioners (CNS/NP); Group 3 were subjects who reported they were clinical trials nurses (CTN), and Group 4 were subjects who indicated "other" primary position. The four primary positions represent the majority of nurses included in the 2006 ONS membership (Kristina Gantner, personal communication, July 19, 2006).

CHAPTER IV: RESULTS AND SUMMARY

A. Introduction

This study examined oncology nurses' attitudes toward cancer clinical trials, and identified nurses' perceptions of the understanding that patients have about the clinical trial process and the reasons for patient participation in clinical research. This study also investigated factors which may influence oncology nurses' attitudes and perceptions. These factors include age, educational preparation, length of time in oncology nursing, whether or not the nurse actually cares for patients contemplating enrollment or who are currently enrolled in a clinical trial, primary position, and work setting. The investigator believed that all of these factors could influence oncology nurses' attitudes and perceptions. Data were collected from the nurses' answers to the items contained on the modified Nursing Attitudes Survey (NAS) and Demographic Information Form (DIF).

This chapter includes the demographic characteristics of the oncology nurses sampled, psychometric analysis of the modified NAS, the results of the analysis of the research questions, and a summary.

B. Sample

This exploratory study obtained data from a national sample of oncology nurses who were members of the Oncology Nursing Society (ONS). One thousand surveys were mailed, and 357 nurses responded, giving a response rate of 35.7%. Fifty six respondents (15.6%) returned the cover letter and marked the box that indicated they did not meet the inclusion criteria for this study. Two surveys (0.5%) were returned by the U.S. postal service, because the addresses were not valid. The final sample consisted of 301 subjects

who completed the NAS and DIF; therefore, the actual response rate was 30.1%. Table 4 lists the demographic characteristics of the oncology nurses sampled.

Table 4

Demographic Characteristics of Sampled Oncology Nurses (*N* = 301)

Characteristic	*N*	%
Gender		
Male	6	2
Female	259	98
Age (years)		
20-39	64	21.3
≥ 40	236	78.4
No answer	1	0.3
Education level*		
Diploma in nursing	40	13.3
Associate's degree	46	15.3
Bachelor's degree	83	28
Master's degree	93	31
Doctoral degree	39	13
Certification		
OCN®	140	46.5
AOCN®	33	11
AOCNP®	7	2.3
AOCNS®	4	1.3
Other	34	11

* Associate's, bachelor's, master's and doctorate degrees totals combine nursing and other fields

Ninety eight percent (*n* = 259) of the subjects were female, and 2% (*n* = 6) were male. The majority (*n* = 236, 78.4%) reported their age as 40 years old or greater. Thirty-nine (13%) respondents reported that they had a doctoral degree in nursing or another field as their highest education level. The majority of subjects (*n* = 93, 28%) had a master's degree in nursing or another field, followed by 28% (*n* = 83) of subjects who reported that they had a bachelor's degree (in nursing or another field) as their highest education level. Almost one-half (*n* =140, 46.5%) were OCN® certified. Demographic information regarding work setting and primary position was collected.

Table 5 lists work setting and primary position of the nurses sampled.

Table 5

Work Setting and Primary Position

Work setting	*N*	%
In-patient		
BMTU	14	4.7
ICU	2	0.7
Medical-surgical unit-general	1	0.3
Medical-surgical unit-oncology	54	17.9
Oncology specialty unit	25	8.3
Other	20	6.6
No answer	3	1
Outpatient		
Home Care	3	1
Hospital based clinic/infusion center	55	18.3
Physician office	46	15.3
Radiation oncology-Hospital based	11	3.7
Other	25	8.3
No answer	3	1
Other		
Corporate/industry	26	8.6
Extended care facility	1	0.3
HMO	3	1
School of nursing	6	2
Self employed	6	2
Other	12	4
No answer	3	1
Primary position		
Staff nurse	116	38.5
Nurse educator	8	2.7
Nurse manager	17	5.6
Clinical nurse specialist	35	11.6
Clinical trials nurse	17	5.6
Academic educator	4	1.3
Nurse practitioner	45	15
Nurse researcher	8	2.7
Case manager	7	2.3
Other	41	13.6
No answer	3	1

There were two questions on the DIF that asked the subjects to report the number of years as a RN and the number of years as a RN in cancer care. The mean number of years that subjects reported they had RN experience and experience as a RN in cancer care was 20.5 years and 13.23 years, respectively. The minimum number of years as a RN that was reported was 1 year and the maximum was 51 years. For the variable years as a RN in cancer care, the minimum number of years that was reported was 0 and the maximum was 36 (see Table 6).

Table 6

Nurses' Experience in Practice as a RN and a RN in Cancer Care

	Years as a RN	Years as a RN in cancer care
	valid 301	298
N=301	missing 0	3
Mean	20.50	13.23
Median	20.00	12.00
Standard deviation	11.019	8.807
Range	50	36
Minimum	1	0
Maximum	51	36

Nurses indicated "yes" or "no" to a question that asked if they worked with or cared for patients contemplating enrollment or enrolled in clinical trials. More than two thirds of subjects (n = 249) reported that they cared for patients contemplating enrollment in or currently enrolled in clinical trials (see Table 7).

Table 7

Nurses Caring for Clinical Trial Patients

Response	*n*	%
Yes	249	82.7
No	51	16.9
Total	300	99.7
Missing	1	0.3
Total	301	100

Despite this large percentage, the respondents reported that approximately a third of patients (*M* =32.76%, *SD=30.043*) who they care for were offered cancer clinical trial at the nurses' place of employment. The minimum percent of patients offered any type of clinical trial was 0% and the maximum was 100%. However, these data should be interpreted with caution as 58 of the 301 subjects (19.2%) did not answer this question.

C. Psychometric Analysis of the Modified NAS

Factor analysis of the NAS was performed first to determine if the proposed items subscale items grouped together. The underlying assumption of factor analysis is that there exists a number of unobserved latent variables (or "factors") accounting for the correlations among observed variables, such that if the latent variables are partialled out or held constant, the partial correlations among observed variables all become zero (Morrison, 1990). In other words, the latent factors determine the values of the observed variables. The main applications of factor analytic techniques are (a) to reduce the number of variables and (b) to detect structure in the relationships between variables and to classify the variables (Hutcheson & Sofroniou, 1999).

It was anticipated that most of the proposed subscale items would factor together. However, the factor analysis revealed that only some of the proposed item groupings

factored together, while some items factored with others. The investigator found that some items of the proposed subscales factored together, while some other items factored in with different items

Cronbach's alpha for the entire modified NAS, excluding Items 14 and 15, was 0.72. Nunnally and Bernstein (1994) recommended that the alpha be between 0.70-0.90; therefore 0.72 is acceptable, especially for a new instrument used in only two research studies. These data support internal consistency for the total instrument. Any items negatively correlated to the total were rescaled to maintain consistency of attitudinal direction across items within each subscale and the total scale. There are certain circumstances in which the "alpha of some items may be negative; therefore, the data should be recoded if necessary to assure that all items are coded in the same conceptual direction" (De Vellis, 2003, p. 92). Based on these results, the following items on the modified NAS were recoded and the scoring reversed: 2, 9, 10, 13, 22, 23, 24, 25, and 26. For example, the response of Strongly Agree was originally scored as a 5, Somewhat Agree was scored as a 4, Neutral was scored as 3, Somewhat Disagree was scored as a 2, and Strongly Disagree was scored as a 1. The new rescored items were as follows: Strongly Agree = 1, Agree = 2, Neutral = 3, Disagree = 4 and Strongly Disagree = 5.

The construct evaluated by Item 14 was nurses' perceptions of motivations for patient participation in clinical research. Item 14 stated, "Patients participate in research because of:" and 10 subitems (letters A-J) followed with corresponding evaluations using a 5-point Likert scale. Item 14 was the single item to evaluate research Question 4: "What factors do nurses believe influence a patient's decision to participate in a cancer clinical trial?" The Cronbach's alpha for this item was 0.68. Furthermore, Item 15 asked the

subjects for their opinion and instructed them to write a whole number for percent chance that a research drug should have of producing a desired effect before being offered to patients. Cronbach's alpha coefficient reliability is not calculated on single numbers that are not scaled responses (DeVellis, 2003). When items are used to form a scale (or, as in this study, subscales) and the score from the individual item is combined into a single numerical value, the items need to have internal consistency and to be measuring the same thing (Bland & Altman, 1997).

Factor analysis of the modified NAS was computed using principal component factor analysis, and the factors were rotated by varimax rotation. The rotation converged in six iterations to produce four factors or subscales, explaining 40% of the variance. Although the analysis supported some of the original clustering or grouping of items, it showed some items belonged in a different factor (Table 8). Items loading greater than 0.30 would be included in the subscales. Items or variables loading below 0.29 were considered for elimination.

Table 8

Factor Loadings of the Items on the Modified Nurse's Attitude Survey

Subscale items	Factor loadings			
	1	2	3	4
19. Patients understand their prognosis and therapy goals.	0.771			
18. Patients understand their plan of care/treatment.	0.760			
17. Patients' wishes regarding treatment are respected by oncologists.	0.711			
20. Patients' prognoses are usually well explained	0.689			
12. In general, patients are well informed when they choose to participate in a clinical trial.	0.530			
16. Patient's wishes regarding treatment are respected by nurses.	0.492			
21. Patients want to be informed.	0.312			
5. Clinical research improves patient care for the patient involved.		0.682		
8. Patients should be encouraged to participate in research.		0.612		
11. If I had cancer, I would prefer to be treated as part of a clinical trial.		0.572		
6. Hospitals that conduct clinical research have better standards of care than hospitals that do not.		0.541		
1. Conducting research is an important role of oncologists.		0.534		
4. It is appropriate for oncologists to be the person consenting research subjects for their trials, if the research subjects are their own clinic patients		0.463		
3. It is appropriate for oncologists to invite their clinic patients to be subjects in trials that they conduct		0.456		
7. Clinical research in oncology is important in improving standards of care in oncology		0.339		
10. Nurses put too much pressure on patients to participate in clinical trials			0.751	
9. Oncologists put too much pressure on patients to participate in clinical trials			0.724	
2. Clinical research should be conducted only in cancer centers/institutes			0.419	
13. Patients are often unaware that their treatment is part of a research protocol.			0.413	
22. When being told about their therapy, most patients pay more attention to potential benefits of therapy than side effects.				0.702
26. Oncologists believe that patients are willing to accept side effects for even a small benefit of therapy				0.662
23. Most patients are willing to accept side effects for even a small benefit if therapy.				0.611
24. Patients are often frightened to ask questions.				0.504
25. Patients' decisions whether to accept or not accept toxic chemotherapy is strongly influenced by their family preferences.				0.361

Extraction Method: Principal Component Analysis. Rotation Method: Varimax with Kaiser Normalization. Rotation converged in 6 iterations.

Each item loaded strongly on one and only one factor and lends to the validity of the subscales. A promax rotation of the principal components procedure also was investigated to determine whether the items consistently loaded on the same factors and to inspect the interfactor correlations. The items did load on the same factors, as in the varimax rotation, indicating that each subscale is measuring a unique and independent construct. The low correlation values (0.005 to 0.274) indicate very low to no correlation or little to no linear relationship between the four subscales. Table 9 presents the interfactor correlations for the four subscales of the instrument. With these very low correlations in the factor analytic procedure, it is not necessary to discuss a total scale score since the factors are measuring unique and independent constructs (DeVellis, 2003).

Table 9

Interfactor Correlation of Identified Factors

	Subscale 1	Subscale 2	Subscale 3	Subscale 4
Subscale 1	1.00			
Subscale 2	0.274	1.00		
Subscale 3	0.231	0.126	1.00	
Subscale 4	0.009	0.007	0.005	1.00

There were four subscales created: Patient Understanding and Knowledge (PUK), Attitude Toward Clinical Research (ATCR), Roles and Location (RL), Information Needs of Patients (INP). Table 10 illustrates the details of the four subscales created from the factor analysis of the modified NAS.

Table 10

Subscales Created After Factor Analysis

Subscale	No of items	Cronbach's Alpha	No of items reversed	Range of scores SA* --- SD**
1. Patient understanding and knowledge (PUK)	7	0.74	0	SA 35 to SD 7
2. Attitude towards clinical research (ATCR)	8	0.66	0	SA 40 to SD 8
3. Roles and location (RL)	4	0.47	4	SA 4 to SD 20
4. Information needs of patients (INP)	5	0.56	5	SA 5 to SD 25

*SA = strongly agree **SD = strongly disagree

Subscale 1—Patient Understanding and Knowledge

Items 12, 16, 17, 18, 19, 20, and 21 make up the Patient Understanding and Knowledge (PUK) subscale. This subscale measured a nurse's perception of patient understanding and knowledge. For example, items on this subscale inquire about patients being well informed when they participate in clinical trials (Item 12), patients understanding their treatment plans and prognosis (Items 18, 19, and 20). The calculated Cronbach's alpha for the PUK subscale was 0.74, indicating the PUK subscale has a fairly high level of internal consistency and reliability. The PUK subscale was used as the measure for research Question 3 (see Analysis of Research Questions in this chapter)

Subscale 2—Attitudes Toward Clinical Research

Subscale 2, the Attitudes Toward Clinical Research subscale (ATCR) is comprised of Items, 1, 3, 4, 5, 6, 7, 8, and 11. This subscale measures nurses' general attitudes toward clinical research. For example, the items ask about: clinical research improving standards of care (Items 5, 6, and 7), if patients should participate in research (Item 8), and if a person completing the instrument would participate in a clinical trial if

they had cancer (Item 11). This subscale was the dependent variable to answer research Question 1 (see analysis of research questions in this chapter). Cronbach's alpha for this scale was 0.66.

Subscale 3—Roles and Location

Four items factored together to form Subscale 3, the Roles and Location subscale (RL), that is comprised of Items 2, 9, 10 and 13. These items measured clinical research location and the role of oncologists and nurses in patient enrollment. For example, some items asked if nurses or oncologists put too much pressure on patients to participate in clinical trials (Items 9 and 10), and if clinical research should be conducted only in cancer centers (Item 2). This subscale was used as the dependent measure for research Question 6 (see Analysis of Research Questions in this chapter). Cronbach's alpha for this subscale was 0.47. The alpha was not as high as the first two subscales, but it has fewer items. Reliability is affected by the number of items in the subscale and the smaller number of items in this subscale may be reflecting this attribute (Ary, Jacobs, & Razavieh, 2002).

Subscale 4—Information Needs of Patients

The final five items that factored together were 22, 23, 24, 25, and 26, forming the Information Needs of Patients (INP) subscale. This subscale measured a nurse's perception of the informational needs of patients. Some items asked if most patients pay more attention to potential benefits of therapy than side effects (Item 22), if oncologists believe that patients are willing to accept side effects for even a small therapeutic benefit (Item 26), if most patients are willing to accept side effects for even a small benefit of therapy (Item 23), if patients are frightened to ask questions and if patients decisions are influenced by their family preferences (Items 24 and 25). This subscale was used as the

dependent variable to answer research Question 5 (see Analysis of Research Questions in this chapter). The calculated Cronbach's alpha for the INP subscale was 0.56. While the alpha was not very high, it is acceptable for this type of measure, because the few number of items may be affecting the reliability coefficients.

Reliability can be affected by several factors, the length of the test or number of items on a survey; the longer it is, the greater the reliability. Reliability also is a function of the person taking the test; a test may be reliable at one level of ability but unreliable at another level of ability. Finally, some variables will yield consistent measures more often than other variables. For example, academic achievement measures tend to have higher reliability compared to softer measures such as attitudes and personality which are often not as reliable (Ary, Jacobs, & Razavieh, 2002).

D. Analysis of Data According to Research Questions

Research Question 1

Research Question 1 - What are oncology nurses' attitudes toward the benefits of cancer clinical trials? This question was evaluated by the ATCR subscale. The nurses responded to these items using a 5-point Likert scale: 1 = strongly disagree; 2 = somewhat disagree; 3 = neither; 4 = somewhat agree and 5 = strongly agree. The outcome variables were created by summing across the items in each subscale. The mean summed scores were used for comparison. There are eight items that make up this subscale and the possible average score per response are: 8 = strongly disagree, 16 = somewhat disagree, 24 = neutral, 32 = somewhat agree, and 40 = strongly agree. The possible range of scores is 8–40. The higher the score is, the more positive are the attitudes of nurses toward clinical research and clinical trials.

From this study population (*N=301)*, 299 subjects responses were analyzed by the ACTR subscale. The mean and median scores obtained were 32, indicating, on the average, the oncology nurses had positive attitudes toward cancer clinical trials. When the mean and median values are the same number, it indicates that the sample distribution is symmetrical, as in a normal distribution curve (Stevens, 2002). The scores on the ATCR subscale ranged from 13 to 40.

Research Question 2

Research Question 2 - What are nurses perceptions about how effective a research drug or experimental therapy should be before it is offered to patients? This question was evaluated by a single item on the NAS, item 15. This item states, "In your opinion, in order for a research drug or experimental therapy to be offered to patients, it should have at least _____% chance of producing a desired effect (please insert a number)." In general, before a research drug or experimental therapy is offered to a patient, the subjects perceived that the benefit should be high, 288 (95.7%) answered this question. Approximately half of the respondents (49.7%) believed that a research drug or experimental therapy should have at least a 50% chance of benefiting the patient before being offered (M = 41.57, SD = 22.76). Subjects' answers to Item 15 ranged from 0% to 95%

Research Question 3

Research Question 3 - What are oncology nurses' perceptions regarding patients' understanding of clinical trials and the treatment regimen? This question was evaluated by the PUK subscale, comprised of Items 12, 16, 17, 18, 19, 20, and 21. These items were evaluated using a 5-point Likert scale. The outcome variables were the sum scores

generated from the subscale, with a possible range of 7–35. Because there are seven items on this subscale, the possible average scores are: 7 = strongly disagree, 14 = somewhat disagree, 21 = neutral, 28 = somewhat agree, and 35 = strongly agree. A higher score suggests that nurses are more likely to believe that patients are well informed about clinical trials, understand the treatment regimen, and desire to be informed.

All 301 subjects completed the items on the PUK subscale. The mean score was 27.6, and the median was 28, indicating this group of oncology nurses agreed that patients are well informed about clinical trials, understand the treatment regimen, and desire to be informed. The mean and median scores are nearly identical indicating that the distribution of data are nearly symmetrical and follow a normal distribution curve (Stevens, 2002).

Research Question 4

Research Question 4 - What factors do nurses perceive influence a patient's decision to participate in a cancer clinical trial? This question was evaluated by Item14 on the NAS. The item asks, "Patients participate in research because of," and there are 10 subitems (letters A-J), with corresponding evaluations using a 5-point Likert scale. The 10 subitems were ranked from highest to lowest according to the percentage of subjects who selected number 4 or 5 (somewhat agree or strongly agree) on the Likert scale. Ninety-three percent of nurses thought that patients participated in research with the expectation of cure; 87% reported that patients participated as a desire to help others; 86% thought patients wanted an improved quality of life (see Table 11).

Table 11

Nurses' Perceptions of Patient Motivation for Participation in Clinical Trials (N = 301)

Motivation	*n*	%
Wish for cure	280	93
Wish to help others	262	87
Wish for improved quality of life	261	86
Hope for better medical care	229	76
No other option	219	73
Inability to accept that nothing else can be done	187	62
Family wishes	169	56
Inability to accept death	158	53
Desire to please their oncologist	85	28
Pressure from oncologist	39	13

Research Question 5

Research Question 5 - What are nurses' perceptions of patients' decision-making processes and the desire for information regarding clinical trial participation? This question was addressed by Items 22, 23, 24, 25, and 26 of the INP subscale. After completing the factor analysis to confirm the items relationship with each other, the outcome variables were sum scored with a possible range of 5–25. The items on the INP scale were reverse coded (strongly agree = 1, somewhat agree = 2, neutral = 3, somewhat disagree = 4, and strongly disagree = 5). The possible scores for each Likert item follows: 5 = strongly agree, 10 = somewhat agree, 15 = neutral, 20 = somewhat disagree, and 25 = strongly disagree, with a lower score suggesting that nurses perceive that patients have

enough information to make decisions regarding clinical trial participation. The minimum score on the INP subscale was 5 and the maximum 19. From the entire study population (N = 301), 299 (99.3%) responded to the items on the INP subscale. The mean score obtained was 10.9, and the median was 11, indicating that on average, this group of oncology nurses perceived that patients have enough information to make decisions regarding clinical trial participation. The mean and median scores almost are identical indicating that the distribution of data is nearly symmetrical and follows a normal distribution curve (Stevens, 2002).

Research Question 6

Research Question 6 - What are the perceptions of nurses regarding where clinical research should be conducted and the role of oncologists and nurses in clinical trials? This question was evaluated by the RL subscale, consisting of items 2, 9, 10, and 13. A 5-point Likert scale was used for these items. Items on the subscale were reverse coded, with strongly agree = 1, somewhat agree = 2, neutral = 3, somewhat disagree = 4, and strongly agree = 5. The outcome variables were sum scored with possible range of 4–20. The possible average scores for each item are; 4 = strongly agree, somewhat agree = 8, neutral = 12, somewhat disagree = 16, and strongly disagree = 20. A lower score suggests agreement with the items on the subscale, such as clinical research should be conducted only in cancer centers, oncologists and nurses put too much pressure on patients to participate in clinical trials, and patients often are unaware that their treatment is part of a research protocol. Three hundred of the 301 subjects responded to the items on the RL subscale. The mean score was 15.4, and the median was 16, indicating this group of oncology nurses somewhat disagreed that clinical research should be conducted

only in cancer centers, oncologists and nurses put too much pressure on patients to participate in clinical trials, and patients often are unaware that their treatment is part of a research protocol. Consistent with the scores obtained on the ATCR, PUK, and INP subscales, the mean and median scores nearly are identical, indicating that the data follow a normal distribution curve (Stevens, 2002).

Research Question 7

Question 7 - Do the independent variables of nurses' age, education level, whether nurses directly work with clinical trial patients, number of years in oncology, primary work setting, and their primary position serve as significant predictors related to:

1. Attitudes toward the benefits of cancer clinical trials, measured by ATCR subscale?

2. Attitudes about how effective a research drug or experimental therapy should be shown to be before it is offered to patients, measured by Item 15 on the NAS?

3. Perceptions regarding patients' understanding of clinical trials and the treatment regimen, as measured by the PUK subscale?

4. Perceptions of patients' decision-making processes and the desire for information regarding clinical trial participation, as measured by the INP subscale?

5. Perceptions regarding where clinical research should be conducted, patients' awareness of their treatment, and the role of oncologists and nurses in clinical trials, as measured by the RL subscale?

Oncology nurses' attitudes toward the benefit of cancer clinical trials were evaluated by the ATCR subscale. Using the stepwise multiple regression method, nurse's primary position entered the stepwise regression model as a significant predictor of

attitudes toward cancer clinical trials (as measured by the ATCR subscale), controlling for the other independent variables, F (1, 228) = 37.555, p <0.001. However, the R^2 = 0.141, indicated the model accounted for only 14.1% of variance in attitude scores. The β coefficient is 0.376, indicating primary position has a low effect on the ATCR subscale; however, the effect was statistically significant (t = 6.128, p<0.001) (see Table 12).

Table 12

Table 12 Stepwise Regression Model Summary for ATCR subscale

Predictor	R	R^2	R_{2adj}	F_{chg}	p
Primary position	0.378	0.141	0.138	37.555	<0.001
	B	β	t	p	
Primary position	1.466	0.376	6.128	<0.001	

ANOVA demonstrated statistically significant differences between the mean scores of nurses grouped within the primary position variable, F (3,248) = 10.322, p = 0.000 (Table 13). This group included staff nurses, clinical trials nurses (CTN) , clinical nurse specialist/nurse practitioners (CNS/NP) and "other."

Table 13

ANOVA for Primary Position and ATCR Subscale

Groups (Primary position)	N	M	SD	df	F	P
Staff nurse	114	30.5	4.2	3, 248	10.322	0.000
CNS/NP	80	32.0	4.0			
CTN	17	33.6	2.9			
Other	41	34.1	3.5			

A Bonferroni post-hoc multiple comparisons test between the primary position variables was conducted to determine which groups had statistically significant

differences in their mean ATCR scores (Table 14). CTN had statistically significant higher scores compared to staff nurses (p = 0.014) only. Nurses in "other" positions had significantly higher scores on the ATCR, compared to staff nurses and CNS/NP (p = 0.000 and 0.026, respectively).

Table 14

Bonferroni Multiple Comparisons for Primary Position and ATCR Subscale

Dependent variable	(I) Primary position	(J) Primary position	Mean difference (I-J)	Std. error	*P*
ATCR subscale	Staff nurse	CNS/NP	-1.4750	0.5734	0.064
		CTN	-3.1471(*)	1.0222	0.014
		Other	-3.6463(*)	0.7160	0.000
	CNS/NP	Staff nurse	1.4750	0.5734	0.064
		CTN	-1.6721	1.0500	0.675
		Other	-2.1713(*)	0.7551	0.026
	CTN	Staff nurse	3.1471(*)	1.0222	0.014
		CNS/NP	1.6721	1.0500	0.675
		Other	-0.4993	1.1341	1.000
	Other	Staff nurse	3.6463(*)	0.7160	0.000
		CNS/NP	2.1713(*)	0.7551	0.026
		CTN	0.4993	1.1341	1.000

* The mean difference is significant at < 0 .05 level.

Even though work setting was not a predictive variable for the ATCR subscale, nurses grouped by this setting also had significant differences in their ATCR scores, $F(5,262) = 5.156$, $p = 0.000$ (see Table 15). This group included bone marrow transplant/intensive care unit nurses (BMTU/ICU), in-patient medical-surgical oncology unit and oncology specialty unit nurses (MSOU), hospital based clinic/infusion center nurses (HBIC), corporate/industry nurses (CI), and "other."

Table 15

ANOVA for Primary Work Setting and ATCR Subscale

Groups (work setting)	*N*	*M*	*SD*	*df*	*F*	*P*
BMTU/ICU	15	30.7	2.6	5, 262	5.156	0.000
MSOU	79	30.9	4.2			
HBIC	55	32.2	4.3			
MDO	45	31.3	4.5			
CI	26	35.0	3.3			
Other	56	33.0	3.6			

To determine which of the five different practice setting groups had significant differences in their ATCR subscale scores, the data were analyzed with a Bonferroni post- hoc multiple comparison test. Nurses who reported that they work in a corporate/industry (CI) work setting had significantly higher scores on the ATCR (M = 35.0) compared to BMTU/ICU nurses (M = 30.7, p = 0.019), medical-surgical oncology unit (MSOU) nurses (M = 30.9, p = 0.000), and physician office (MDO) nurses (M = 31.3, p = 0.003). Table 16 presents the results of the Bonferroni pairwise comparisons for primary work setting.

Table 16

Bonferroni Multiple Comparisons for Primary Work Setting and ATCR Subscale

Dependent variable	(I) Work setting	(J) Work setting	Mean difference (I-J)	Std. error	P
ATCR	BMTU/ICU	MSOU	-0.2111	1.1342	1.000
		HBIC	-1.4519	1.1663	1.000
		MDO	-0.5333	1.1914	1.000
		CI	-4.2282(*)	1.2956	0.019
		Other	-2.2488	1.1618	0.810
	MSOU	BMTU/ICU	0.2111	1.1342	1.000
		HBIC	-1.2407	0.7194	1.000
		MDO	-0.3222	0.7594	1.000
		CI	-4.0171(*)	0.9143	0.000
		Other	-2.0377	0.7120	0.068
	HBIC	BMTU/ICU	1.4519	1.1663	1.000
		MSOU	1.2407	0.7194	1.000
		MDO	0.9185	0.8066	1.000
		CI	-2.7764	0.9539	0.059
		Other	-0.7970	0.7621	1.000
	MDO	BMTU/ICU	0.5333	1.1914	1.000
		MSOU	0.3222	0.7594	1.000
		HBIC	-0.9185	0.8066	1.000
		CI	-3.6949(*)	0.9844	0.003
		Other	-1.7155	0.8000	0.494
	CI	BMTU/ICU	4.2282(*)	1.2956	0.019
		MSOU	4.0171(*)	0.9143	0.000
		HBIC	2.7764	0.9539	0.059
		MDO	3.6949(*)	0.9844	0.003
		Other	1.9794	0.9483	0.567
	Other	BMTU/ICU	2.2488	1.1618	0.810
		MSOU	2.0377	0.7120	0.068
		HBIC	0.7970	0.7621	1.000
		MDO	1.7155	0.8000	0.494
		CI	-1.9794	0.9483	0.567

* The mean difference is significant at < 0 .05 level.

Item 15 on the NAS asked subjects their perceptions on the effectiveness (expressed in percent benefit) of a research drug or experimental treatment before it is offered to patients. The multiple regression analysis revealed a significant model, primary position, years experience as a cancer RN, work setting, and educational level were

predictors of the nurse's opinion of the effectiveness of a research drug or experimental treatment before being offered to a patient, F (4, 218) = 9.164, p = 0.000 . However, the R^2 was 0.144, indicating the model has accounted for only 14.4% of the variance in perceived benefit estimates (see Table 17).

Table 17

Stepwise Regression Model Summary for Perception of Benefit

Predictor	R	R^2	R_{2adj}	F_{chg}	p
Primary position	0.379	0.144	0.128	4.373	0.038
Years cancer RN					
Work setting					
Education level					

Despite this model being statistically significant for predicting the opinion of the perceived benefit of the effectiveness a research drug or experimental treatment should have before being offered to a patient, the β regression coefficients were low for each predictor variable (see Table 18). This indicates primary position, years in cancer nursing, work setting, and education level had a low effect on the perceived benefit. Only the effect of years a cancer RN, work setting, and education level were statistically significant (t = 2.091, p = 0.038; t = 2.417, p = 0.016; t = 2.091, p = 0.038 respectively).

Table 18

Stepwise Regression Coefficients for Perception of Benefit Model

	B	β	t	P
Primary position	-2.783	-0.127	1.701	0.090
Years cancer RN	-0.373	-0.137	2.091	0.038
Work setting	-2.578	-0.172	2.417	0.016
Education level	-1.519	-0.144	2.091	0.038

In addition to the variables of primary position, years as a cancer RN, work setting and educational level, being predictors of the nurses' perceptions of the benefit of effectiveness a research drug or experimental treatment should have before being offered to a patient, statistically significant differences were found between these groups of nurses' responses when ANOVA was performed.

Primary position. Staff nurses reported the highest perception of benefit regarding the effectiveness of a research drug or experimental therapy, before being offered to patients compared to nurses in other positions. According to the results from the ANOVA of primary position and the opinion of the benefit of an experimental treatment before being offered as part of cancer therapy, there were statistically significant differences in this group F (3, 239) = 8.499, p = 0.000 (see Table 19).

Table 19

ANOVA of Primary Position and Perception of Benefit

Groups (Primary Position)	*N*	*M* %	*SD*	*Df*	*F*	*P*
Staff nurse	114	49.3	22.6	3, 239	8.499	0.000
CNS/NP	74	34.6	21.1			
CTN	16	36.3	26.3			
Other	39	35.1	21.2			

The investigator performed a Bonferroni multiple comparisons for primary position and nurse's opinion of the effectiveness of a research drug or experimental therapy before being offered to a patient (see Table 20). Staff nurses had significantly higher perceptions of the benefit a research drug or experimental therapy should have

before being offered to patients, compared to CNS/NPs (p = 0.000) and nurses in "other" positions (p = 0.004), but not between any other positions (see Table 20).

Table 20

Bonferroni Multiple Comparisons for Primary Position and Perception of Benefit

Dependent variable	(I) Primary position	(J) Primary position	Mean difference (I-J)	Std. error	P
Perception of Benefit	Staff nurse	CNS/NP	14.72(*)	3.31	0.000
		CTN	13.09	5.93	0.169
		Other	14.29(*)	4.12	0.004
	CNS/NP	Staff nurse	-14.72(*)	3.31	0.000
		CTN	-1.63	6.12	1.000
		Other	-0.43	4.39	1.000
	CTN	Staff nurse	-13.09	5.93	0.169
		CNS/NP	1.63	6.12	1.000
		Other	1.20	6.59	1.000
	Other	Staff nurse	-14.29(*)	4.12	0.004
		CNS/NP	0.43	4.39	1.000
		CTN	-1.20	6.59	1.000

* The mean difference is significant at < 0 .05 level.

Number of years in cancer nursing. Nurses with 10 or less years of experience had the highest perception of benefit of cancer therapy prior to being offered as part of research. This group reported that a research drug, or experimental therapy, should have at least a 46.2% (mean) chance of producing a desired effect before being offered to patients. In contrast, nurses with greater than 20 years experience in cancer nursing had the lowest perceived benefit. They reported that a therapy should have at least a 35% (mean) chance of producing the desired effect. Nurses with 11-20 years of experience in cancer nursing reported a research drug, or experimental therapy, should have at least a 40.2% (mean) chance of producing the desired effect. The ANOVA for number of years in cancer nursing and perceptions regarding the effectiveness of cancer therapy offered as

part of research revealed statistically significant differences between the three groups F (2, 281) = 5.318, p = 0.005 (see Table 21).

Table 21

ANOVA for Number of Years in Cancer Nursing and Perception of Benefit

Groups (Years a cancer RN)	*N*	*M* %	*SD*	*df*	*F*	*P*
<1–10	130	46.2	22.2	2, 281	5.318	0.005
11–20	98	40.2	23.1			
>20	56	35.1	21.2			

In order to examine which group had statistically significant differences in their perception of benefit a research drug or experimental therapy should have before being offered to patients, a Bonferroni multiple comparisons test was performed (see Table 22). This test revealed that nurses with greater than 20 years experience had a statistically significant difference in their opinion compared to nurses with 10 years or less experience (p = 0.006), but not with nurses who had 11–20 years experience (p = 0.522). Moreover, there was no a statistically significant difference in the opinions of nurses with 10 or less years experience compared to nurses with 11–20 years experience (p = 0.134).

Table 22

Bonferroni Multiple Comparisons for Years in Cancer Nursing and Perception of Benefit

Dependent variable	(I) Yrs CN	(J) Yrs CN	Mean difference (I-J)	Std. error	P
Perception of Benefit	<1-10	11-20	6.03	2.99	0.134
		>20	11.12(*)	3.57	0.006
	11-20	<10	-6.03	2.99	0.134
		>20	5.10	3.74	0.522
	>20	<1-10	-11.12(*)	3.57	0.006
		11-20	-5.10	3.74	0.522

* The mean difference is significant at < 0 .05 level.

Primary work setting. There were statistically significant differences found in the responses of the subjects, grouped by work setting, regarding the desired effect a research drug, or experimental therapy should have, before being offered to patients in the subjects grouped by work setting F (5, 253) = 6.450, p = 0.000 (see Table 23).

Table 23

ANOVA of Primary Work Setting and Perception of Benefit

Groups (work setting)	*N*	*M* %	*SD*	*Df*	*F*	*P*
BMTU/ICU	14	48.9	24.4	5, 253	6.450	0.000
MSOU	71	51.4	22.6			
HBIC	51	35.1	20.1			
MDO	46	41.2	23.8			
CI	25	27.2	21.6			
OTHER	52	39.0	19.4			

The nurses who reported that they worked in a corporate /industry (CI) setting had perceived a lower benefit (M = 27.2%) of the effectiveness a research drug or experimental therapy should have before being offered to patients, compared to all other nurses in this group. Furthermore, nurses who reported that they worked in an inpatient setting on a medical-surgical oncology unit or an oncology specialty unit (MSOU) had the highest perceived benefit (M = 51.4%), compared to other nurses in this group

Nurses working in an inpatient setting on MSOU had a statistically significant higher perception of benefit of the effectiveness a research drug or experimental therapy should have before being offered to patients, compared to HBIC nurses (p = 0.001), to nurses in a CI setting (p = 0.000) and to nurses in other settings (p = 0.030). Nurses working in BMTU/ICU as well as MSOU nurses statistically had a significant higher perception compared to nurses in a corporate/industry setting (p = 0.045 and p = 0.000,

respectively). All other comparisons between the groups were not statistically significant (see Table 24).

Table 24

Bonferroni Multiple Comparisons for Work Setting and Perception of Benefit

Dependent variable	(I) Work setting	(J) Work setting	Mean difference (I-J)	Std. error	P
Opinion	BMTU/ICU	MSOU	-2.44	6.36	1.000
		HBIC	13.87	6.56	0.532
		MDO	7.75	6.64	1.000
		CI	21.73(*)	7.26	0.045
		Other	9.95	6.55	1.000
	MSOU	BMTU/ICU	2.44	6.36	1.000
		HBIC	16.31(*)	3.99	0.001
		MDO	10.19	4.11	0.209
		CI	24.17(*)	5.06	0.000
		Other	12.39(*)	3.97	0.030
	HBIC	BMTU/ICU	-13.87	6.56	0.532
		MSOU	-16.31(*)	3.99	0.001
		MDO	-6.12	4.42	1.000
		CI	7.86	5.31	1.000
		Other	-3.92	4.28	1.000
	MDO	BMTU/ICU	-7.75	6.64	1.000
		MSOU	-10.19	4.11	0.209
		HBIC	6.12	4.42	1.000
		CI	13.97	5.40	0.154
		Other	2.19	4.40	1.000
	CI	BMTU/ICU	-21.73(*)	7.26	0.045
		MSOU	-24.17(*)	5.06	0.000
		HBIC	-7.86	5.31	1.000
		MDO	-13.97	5.40	0.154
		Other	-11.78	5.29	0.403
	OTHER	BMTU/ICU	-9.95	6.55	1.000
		MSOU	-12.39(*)	3.97	0.030
		HBIC	3.92	4.28	1.000
		MDO	-2.19	4.40	1.000
		CI	11.78	5.29	0.403

* The mean difference is significant at <0.05 level.

Education level. Nurses with a bachelor's degree had the highest perception of benefit of a research drug or experimental treatment producing a desired effect before

being offered to patients (M = 47.4%, SD = 22.3), compared to other nurses in this sample. In contrast, nurses with a master's degree or higher indicated the lowest perception of the three groups (M = 35.6%, SD = 21.1). There was a statistically significant difference in the responses of the three groups according to education preparation F (2, 284) = 8.087, p = 0.000 (see Table 25).

Table 25

ANOVA for Educational Level and Perception of Benefit

Education groups	*N*	*M %*	*SD*	*df*	*F*	P
Diploma or associate's	86	45.0	23.6	2, 284	8.8087	0.000
Bachelor's degree	79	47.4	22.3			
Master's or higher	122	35.6	21.1			

Nurses with a master's degree or higher statistically had a significant difference in their mean responses when compared to nurses with a bachelors degree and nurses with any degree less than a bachelor's (p = 0.001, p = 0.009, respectively). This result indicates that nurses with a master's degree or higher perceived the least necessary benefit compared to other nurses with lesser educational degrees. They reported a research drug or experimental therapy should have a 35.6% (mean) chance of producing a desired effect before being offered to patients (see Table 26).

Table 26

Bonferroni Multiple Comparisons for Education Level and Perception of Benefit

Dependent variable	(I) Education groups	(J) Education groups	Mean difference (I-J)	Std. error	P
Perception of Benefit	Diploma or associates	Bachelor's	-2.41	3.46	1.000
		Master's or higher	9.34(*)	3.13	0.009
	Bachelor's	Diploma or associates	2.41	3.46	1.000
		Master's or higher	11.76(*)	3.21	0.001
	Master's or higher	Diploma or associates	-9.34(*)	3.13	0.009
		Bachelor's	11.76(*)	3.21	0.001

* The mean difference is significant <0.05 level

Nurse's perception of patient knowledge and understanding of the treatment regimen was evaluated by the PUK subscale. Multiple regression analysis revealed nurse's education level, work setting, and whether they work with clinical trial patients or not were significant predictors of their perceptions of patient knowledge and understanding, F (3, 228) = 4.846, p = 0.003. The R^2 was 0.060, indicating the model accounted for only 6% of the variance in perceptions (see Table 27).

Table 27

Stepwise Regression Model Summary for PUK subscale

Predictors	R	R^2	R_{2adj}	F_{chg}	p
Education level, Work setting, Trials	0.245	0.060	0.048	5.705	0.018

The β regression coefficients for the model were low (see Table 28), indicating educational level, work setting, and working with clinical trial patients or not had a low

effect on perceptions. However, the effect of education level, work setting and whether they work with clinical trial patients or not was significant (t = 2.432, $p = 0.016$; t = 2.442, $p = 0.015$; and t = 2.388, $p = 0.00018$, respectively).

Table 28

Stepwise Regression Coefficients for PUK Model

	B	*β*	*t*	*P*
Ed level	-0.274	- 0.158	2.432	0.016
Work setting	0.394	0.159	2.442	0.015
Trials	1.605	0.155	2.388	0.00018

Despite education level being a significant predictor for oncology nurses' perceptions regarding patients' understanding of clinical trials and the treatment regimen, there were no significant differences between the scores on the PUK subscale in this group. However, after performing ANOVA for nurses working with clinical trial patients or not, and nurses grouped by work setting revealed significant differences in their scores on the PUK subscale.

Working with clinical trial patients. Nurses who work with clinical trial patients had a higher mean score on the PUK subscale compared to nurses who do not (27.9 and 26.5, respectively), indicating that nurses who work with clinical trial patients perceive patients understand their treatment goals, plan, and prognosis, and their wishes are respected by oncologists and nurses. The differences in their scores were statistically significant, F (1, 298) = 5.292, $p = 0.022$ (see Table 29).

Table 29

ANOVA for Working with Clinical Trial Patients or Not and PUK Subscale

Groups	*N*	*M*	*SD*	*Df*	*F*	*P*
No	51	26.5	4.5	1,298	5.292	0.022
Yes	249	27.9	3.6			

Work setting. Two groups of nurses reported they worked in an outpatient setting, HBIC and MDO nurses, had higher scores on the PUK (28.8 and 28.2, respectively) compared to the other nurses. This result suggests HBIC and MDO nurses perceive that patients are well informed when they participate in clinical trials and patients understand their treatment plan and prognosis, compared to BMTU/ICU, MSOU, and CI nurses. The nurses working in BMTU/ICU, MSOU, CI and nurses in other settings all had similar scores on the PUK (26.2, 27.0, 26.5, and 28.0, respectively). ANOVA was calculated for differences between the subjects grouped by work setting and a statistically significant difference was found, F (5, 264) = 2.516, p = 0.030 (see Table 30).

Table 30

ANOVA for Work Setting and PUK Subscale

Groups (work setting)	*N*	*M*	*SD*	*df*	*F*	*P*
BMTU/ICU	15	26.2	3.8	5, 264	2.516	0.030
MSOU	73	27.0	4.0			
HBIC	54	28.2	3.6			
MDO	46	28.8	4.1			
CI	26	26.5	4.3			
Other	56	28.0	3.2			

Despite finding a statistically significant difference in the groups' scores by ANOVA, surprisingly the Bonferroni post-hoc multiple comparisons test failed to identify which group differed from which. This discrepancy may be explained by two factors. First, the variance between groups is not big enough to make a difference. With unequal sample sizes within each group, the small differences between groups may be cancelled in the post-hoc, pairwise comparisons. Secondly, the more groups that have a large variation in sample size, the harder it is to detect significant differences between groups, especially with a rigorous and conservative test such as Bonferroni to avoid type I error (Keppel & Wickens, 2002).

The INP subscale measured nurse's perceptions of patients' perceptions of the treatment and research process and influences in patients' decisions. As stated above, the items on this subscale were reverse coded (strongly agree = 1, somewhat agree = 2, neutral = 3, somewhat disagree = 4, and strongly disagree = 5) with a lower score suggesting that nurses perceive that patients have enough information to make decisions regarding clinical trial participation.

The multiple regression analysis revealed a significant model, whether nurses work with clinical trials patients or not, F (1, 228) = 5.798, p =.017. The R^2 = 0.025, indicating the model accounted for only 2.5% of the variance in perceptions (see Table 31).

Table 31

Stepwise Regression Model Summary for INP Scale

Predictor	R	R^2	R_{2adj}	F_{chg}	p
Trials	0.157	0.025	0.021	5.798	0.017

The β regression coefficient for the predictor variable was 0.157 (see Table 32). This indicates that the variable (nurse's working with clinical trial patients or not) had a low effect on perceptions, as measured by the INP subscale despite a statistically significant multiple regression model.

Table 32

Stepwise Regression Coefficients for INP Model

Predictor	*B*	*β*	*t*	*P*
Trials	1.058	0.157	2.408	0.017

Nurses grouped by whether or not they work with clinical trial patients was the only significant predictor of perceptions of patients' decision-making process and desire for clinical trial information. However, in evaluating differences in the mean scores among the oncology nurses in this study grouped by the independent variables, statistically significant differences were found in this group and nurses grouped by work setting.

Working with clinical trial patients. Nurses who reported that they do not work with or care for clinical trial patients had a lower score ($M = 10.1$), compared to nurses who do ($M = 11.0$). This result suggests nurses who do not work with clinical trial patients perceive that most patients pay more attention to potential benefits of therapy than side effects, oncologists believe that patients are willing to accept side effects for a small therapeutic benefit, patients are frightened to ask questions, and patients' decisions are influenced by their family's preferences, compared to nurses who do work with clinical trial patients. This difference was statistically significant, $F(1, 296) = 5.872$, $p = 0.016$ (see Table 33).

Table 33

ANOVA for Working with Clinical Trial Patients or Not and INP Subscale

Groups	*N*	*M*	*SD*	*df*	*F*	*P*
No	50	10.1	2.4	1, 296	5.872	0.016
Yes	248	11.0	2.6			

Work setting. There were statistically significant differences in the scores on the INP subscale between nurses based upon their work setting, F (5, 262) = 2.762, p = 0.019 (see Table 34).

Table 34

ANOVA for Work Setting and INP Subscale

INP subscale	Groups work setting	*N*	*M*	*SD*	*Df*	*F*	*P*
	BMTU/ICU	15	9.5	2.6	5, 262	2.762	0.019
	MSOU	73	10.8	2.2			
	HBIC	54	11.0	2.5			
	MDO	45	11.9	3.0			
	CI	26	10.9	2.5			
	Other	55	10.5	2.6			

Nurses working in BMTU/ICU had a lower score (M = 9.5) on the INP subscale compared to all other nurses by work setting. This indicates that BMTU/ICU nurses perceive, more than the other four groups, that patients are willing to accept side

effects, pay more attention to the benefits of therapy, have their decisions influenced by their families and are frightened to ask questions. There were statistically significant differences in the scores of BMTU/ICU nurses (M = 9.5) compared to MDO nurses (M = 11.9, p = 0.025). There were no statistically significant differences in the mean scores of the other subjects (see Table 35).

Table 35

Bonferroni Multiple Comparisons for Work Setting and INP Subscale

Dependent variable	(I) Work setting	(J) Work setting	Mean difference (I-J)	Std. error	P
INP Subscale	BMTU/ICU	MSOU	-1.2475	0.7171	1.000
		HBIC	-1.4481	0.7383	0.763
		MDO	-2.4000(*)	0.7541	0.025
		CI	-1.3513	0.8201	1.000
		Other	-0.9212	0.7368	1.000
	MSOU	BMTU/ICU	1.2475	0.7171	1.000
		HBIC	-0.2007	0.4540	1.000
		MDO	-1.1525	0.4794	0.254
		CI	-0.1038	0.5777	1.000
		Other	0.3263	0.4516	1.000
	HBIC	BMTU/ICU	1.4481	0.7383	0.763
		MSOU	0.2007	0.4540	1.000
		MDO	-0.9519	0.5106	0.951
		CI	9.687E-02	0.6038	1.000
		Other	0.5269	0.4846	1.000
	MDO	BMTU/ICU	2.4000(*)	0.7541	0.025
		MSOU	1.1525	0.4794	0.254
		HBIC	0.9519	0.5106	0.951
		CI	1.0487	0.6231	1.000
		Other	1.4788	0.5084	0.059
	CI	BMTU/ICU	1.3513	0.8201	1.000
		MSOU	0.1038	0.5777	1.000
		HBIC	-9.6866E-02	0.6038	1.000
		MDO	-1.0487	0.6231	1.000
		Other	0.4301	0.6020	1.000
	Other	BMTU/ICU	0.9212	0.7368	1.000
		MSOU	-0.3263	0.4516	1.000
		HBIC	-0.5269	0.4846	1.000
		MDO	-1.4788	0.5084	0.059
		CI	-0.4301	0.6020	1.000

* The mean difference is significant at <0.05 level

The RL subscale evaluated nurses' perception of patients' awareness of their treatment and the role of oncologists and nurses in clinical trials. As with the INP subscale, the RL subscale was reverse coded (strongly agree = 1, somewhat agree = 2, neutral = 3, somewhat disagree = 4, and strongly disagree = 5) with a lower score suggesting that nurses perceive clinical research should only be conducted primarily in cancer centers, oncologists and nurses put too much pressure on patients to participate in clinical trials, and that patients often are unaware that their treatment is part of a research protocol.

The multiple regression demonstrated that, years of experience as a cancer RN and whether a nurse works with clinical trial patients as predicators of the perception measured by the RL subscale, F (2, 229) = 6.813, p=.001. The R^2 = 0.056 indicating the predictor variables accounted for only 5.6% of the variance of perceptions (see Table 36).

Table 36

Stepwise Regression Model Summary for RL Subscale

Predictors	R	R^2	R_{2adj}	F_{chg}	p
Years cancer RN Trials	0.237	0.056	0.048	4.630	0.032

The β regression coefficients for the predictor variables of years experience as a cancer RN and whether a nurse worked with clinical trial patients were low (0.182 and 0.139, respectively) (see Table 37). This indicates that while there was statistical significance of the predictor variables, the variables had a low effect on the measurement of perceptions measured by the RL subscale. However, the effect was statistically significant for number of years as a cancer RN and whether or not nurses work with clinical trial patients (t = 2.830, p = 0.005 and t = 2.152, p = 0.32, respectively).

Table 37

Stepwise Regression Coefficients for RL Model

Predictors	*B*	*β*	*t*	*P*
Years cancer RN	0.0056	0.182	2.830	0.005
Trials	0.977	0.139	2.152	0.032

There were significant differences in the mean scores measured by the RL subscale in the nurses grouped by years as a cancer RN and whether or not nurses work with clinical trial patients, but not in any other variables.

Working with clinical trial patients. The ANOVA for this variable demonstrated a statistically significant difference in mean scores of nurses who do and do not work with clinical trial patients, F (1,297) = 10.165, p = 0.002 (see Table 38).

Table 38

ANOVA for Working With Clinical Trial Patients or Not and RL Subscale

RL subscale	Groups	*N*	*M*	*SD*	*df*	*F*	*P*
	No	51	14.4	2.8	1, 297	10.165	0.002
	Yes	248	15.6	2.5			

Nurses who do not work with or care for clinical trial patients had lower scores on the RL subscale (M = 14.4), compared to nurses who do (M = 15.6). This result suggests nurses who do not work with clinical trial patients perceive that clinical research should be conducted only in cancer centers, oncologists and nurses put too much pressure on patients to participate in clinical trials, and patients are often unaware that their treatment is part of a research protocol, compared to nurses who do work with clinical trial patients.

Years experience in cancer nursing. Nurses with less that one to ten years of experience in cancer nursing had lower scores on the RL subscale (M = 14.8), compared to nurses with nurses with 11-20 years of experience (M = 15.8) and nurses with greater than 20 years of experience (M = 15.9). The differences between groups were statistically significant as measured by ANOVA, F (2,294) = 6.027, p = 0.003 (see Table 39).

Table 39

ANOVA for Years in Cancer Nursing and RL Subscale

RL subscale	Groups years a cancer RN	*N*	*M*	*SD*	*df*	*F*	*P*
	<1–10	136	14.8	2.7	2, 294	6.027	0.003
	11–20	98	15.8	2.6			
	>20	62	15.9	2.4			

Nurses with less that one to ten years of experience in cancer nursing had a statistically significant difference in their mean score on the RL subscale, compared to nurses with 11–20 years of experience and nurses with greater than 20 years of experience (p = 0.013, p = 0.014, respectively). Nurses with <1-10 years experience, on average, perceived that clinical research should be conducted only in cancer centers, oncologists and nurses put too much pressure on patients to participate in clinical trials, and patients are often unaware that their treatment is part of a research protocol, compared to nurses with 11 years or greater experience in cancer nursing (see Table 40).

Table 40

Bonferroni Multiple Comparisons for Years in Cancer Nursing and RL Subscale

Dependent variable	(I) Years cancer RN	(J) Years cancer RN	Mean difference (I-J)	Std. error	P
RL Subscale	<1–10	11–0	-0.9696(*)	0.3361	0.013
		>20	-1.1049(*)	0.3888	0.014
	11–20	<1–10	0.9696(*)	0.3361	0.013
		>20	-0.1353	0.4122	1.000
	>20	<1–10	1.1049(*)	0.3888	0.014
		11–20	0.1353	0.4122	1.000

* The mean difference is significant at <0.05 level.

Additional Information

The following information was not part of the research questions; however, interesting data related to individual items within the subscales were found. Although 98.3% of the subjects agreed that clinical research was important in improving future standards of care and 75.4% agreed that patients should be encouraged to participate in research, only 51.5% of subjects responded that they would prefer treatment in a clinical trial if they had cancer.

The nurses in this study drew distinctions between themselves and oncologists in terms of patient decision-making. Ninety-eight percent of the nurses stated that nurses respected patients' wishes, whereas 82.7% thought that oncologists respected patients' wishes. Overall, 8.6% of the nurses agreed with the statement "oncologists put too much pressure on patients to participate in clinical trials." Only 3.3% of the nurses agreed with the statement that "nurses put too much pressure on patients to participate in clinical trials."

The nurses expressed minor concern about patients' understanding of treatment and prognosis. Approximately three quarters of the nurses perceived that patients understand their plan of care (76.4%). Eighty-seven percent of all nurses thought that patients want to be informed, and 80.7% thought that patients actually were well informed when they chose to

participate in a clinical trial. Twenty percent of the nurses disagreed, and 68% agreed with the statement "patients understand their prognosis and goals of therapy." Only 58% of the nurses agreed that patients' prognosis are well explained to them. Overall, 11% of the nurses agreed with the statement "patients are often unaware that their treatment is part of a research protocol." Finally, 66% of the nurses responded that patients are frightened to ask questions.

E. Summary of Results

The nurses in this study, on average, had positive attitudes toward cancer clinical trials. They perceived high benefit levels were necessary before a research drug or experimental therapy is being offered to patients. Approximately half of the respondents (49.7%) believed that an experimental therapy should have at least a 50% chance of producing a desired effect, before being offered to patients. In general, the nurses perceived that patients are well informed about clinical trials, understand the treatment regimen, and have a desire to be informed. On average, this group of oncology nurses perceived that patients have enough information to make decisions regarding clinical trial participation. They somewhat disagreed that; clinical research should be conducted only in cancer centers, oncologists and nurses put too much pressure on patients to participate in clinical trials, and patients are often unaware that their treatment is part of a research protocol.

Stepwise multiple regression models found the following significant predictors to attitudes and perceptions. Primary position was a significant predictor for attitudes toward cancer clinical trials as measured by the ATCR subscale. CTN had more positive attitudes compared to staff nurses, but not other nurses in this group. Nurses in "other" positions had more positive attitudes compared to staff nurses and CNS/NP. Additionally, nurses who

reported that they work in a CI work setting had more positive attitudes toward cancer clinical trials compared to BMTU/ICU nurses, MSOU nurses, and MDO nurses.

Primary position, years as a cancer RN, work setting and educational level were significant predictors of the perception of the benefit a cancer therapy should offer if included in a clinical trial. Staff nurses had the highest expectations regarding the effectiveness of cancer therapy offered as part of a clinical trial, compared to nurses in other positions. The differences were statistically significant between staff nurses compared to CNS/NPs and nurses indicating "other" as position on the DIF, but not among any other nursing positions.

Nurses with 10 or fewer years of experience as a nurse in cancer care had the highest perception of benefit regarding the effectiveness of cancer therapy to be offered as part of research. In contrast, nurses with greater than 20 years of experience in cancer nursing had the lowest perception. There was a statistically significant difference in their opinions compared to nurses' with 10 years or less experience, but not with nurses who had 11–20 years of experience. Moreover, there was no statistically significant difference in the opinions of nurses with 10 or fewer years of experience compared to nurses with 11–20 years of experience.

Nurses who reported that they work in a CI setting had the lowest expectations of the effectiveness of cancer therapy offered as part of a clinical trial compared to all other nurses. Furthermore, nurses who reported they work in an inpatient setting on a MSOU had the highest expectations compared to other nurses. There were statistically significant differences in the opinion of nurses working on a MSOU compared to HBIC nurses, nurses in a CI setting and to nurses in indicating "other" work setting on the DIF. Nurses working in BMTU/ICU as well as MSOU nurses had statistically significant higher expectations, compared to nurses in a CI setting.

Nurses with a bachelor's degree perceived the highest benefit of an experimental treatment producing a desired effect before being offered to patients compared to the other nurses in this group. This was in contrast to nurses with a master's degree or higher who indicated the lowest perception of benefit of the three groups. The nurses with a master's degree or higher had a statistically significant difference in their mean responses, compared to nurses with a bachelor's degree or less.

Multiple regression analysis revealed nurse's education level, work setting, and whether they worked with clinical trial patients or not were significant predictors of their perception of patient knowledge and understanding. Compared to nurses who do not work with clinical trial patients, nurses who work with clinical trial patients perceive that patients understand their treatment goals, plan and prognosis and that their wishes are respected by oncologists and nurses. The differences in the PUK subscale scores were statistically significant. When grouped by work setting, nurses who reported they worked in an outpatient setting (HBIC and MDO) had higher scores on the PUK compared to the other nurses. Even though the ANOVA was statistically significant for the group, the post-hoc multiple comparison test failed to reveal which work settings explained significant differences.

The variable of whether a nurse works with clinical trial patients or not was a significant predictor for perceptions of informational needs of patients, as measured by the INP subscale. Nurses who work with, or care for, clinical trial patients had a statistically significant higher score compared to nurses who do not. This indicates that nurses who do not work with clinical trial patients perceive that patients are willing to accept side effects, pay more attention to the benefits of therapy, have their decisions influenced by their families and are afraid to ask questions. Additionally, statistically significant differences in the INP mean scores were found

between the nurses by work setting groups. BMTU/ICU nurses perceive, more than the other four groups, that patients are willing to accept side effects, pay more attention to the benefits of therapy, have their decisions influenced by their families and are afraid to ask questions. There were statistically significant differences in their scores on the INP subscale compared to MDO nurses.

The variables, number of years experience as a cancer RN and whether or not a nurse works with clinical trial patients, were significant predicators of the RL subscale. Specifically, differences existed in the perception that nurses have regarding where clinical research should be conducted, patients' awareness of their treatments, and the role of oncologists and nurses in clinical trials. Significant differences were found in the mean scores of nurses who do not work with, or care for, clinical trial patients compared to nurses who do. This suggests nurses who do not work with clinical trial patients perceive that clinical research should be conducted only in cancer centers, oncologists and nurses put too much pressure on patients to participate in clinical trials, and patients often are unaware that their treatment is part of a research protocol, compared to nurses who work with clinical trial patients. Finally, nurses with ten or fewer years of experience, on average, perceived that clinical research should be conducted only in cancer centers, oncologists and nurses put too much pressure on patients to participate in clinical trials, and patients are often unaware that their treatment is part of a research protocol, compared to nurses with 11 years or greater experience in cancer nursing.

CHAPTER V: DISCUSSION AND RECOMMENDATIONS

A. Summary and Discussion of Results

Demographics

The following information regarding the demographic characteristics of the sample is noteworthy. In terms of gender, this sample was consistent with the membership of ONS, the majority of ONS members are female and only 3% of its members are male (Brown, 2003; Kristina Gantner, Personal Communication, July 19, 2006). In this study (N = 301), 98% (n = 295) of the subjects were female and 2% (n = 6) were male. Both the sample and the ONS membership reflected the general nursing population with the majority over the age of 40 (Buerhaus, 2002). Sixty-six percent of ONS members are over the age of 40 (Kristina Gantner, Personal Communication, July 19, 2006).

The proportion of master's prepared nurses in this study is a larger proportion than reported in the ONS membership (ONS, 2004). Nurses in this study with a master's degree (in nursing or any other discipline) as their highest education level, (n = 85) represented 28.2% of the sample. The proportion of subjects with the diploma and associate's degree and bachelor's degrees in nursing in this study was lower than that of the ONS membership.

The major certification category of subjects was OCN®, with 46.5% of the subjects (n = 140) reporting that they had this credential. This is comparable to the proportion of OCN® certified nurses in the ONS membership where 46% report that they have this credential (Kristina Gantner, personal communication, July 19, 2006).

The largest primary work area reported in the study was the outpatient setting 47.3% (n = 141), which is similar to the ONS membership, 51% (Kristina Gantner, personal communication, July 19, 2006). The proportion of nurses working in an in-patient setting was

38.9% (n = 116), which was also similar to the ONS membership, 39%. Finally, the largest proportion of subjects reported that their primary position was staff nurse, 38.5% (n = 116). Proportionally, this is similar to the ONS membership in which staff nurses make up the largest position (Kristina Gantner, personal communication, July 19, 2006).

Relevance of Research to Prior Literature

Research Question 1. – What are oncology nurses' attitudes toward the benefits of cancer clinical trials? The only statistically significant differences found in attitudes toward cancer clinical trials were between nurses grouped by primary position and work setting. Nurses who reported they work in a corporate/industry (CI) setting had a more positive attitude compared to nurses in bone marrow transplant/intensive care unit (BMTU/ICU), in-patient medical-surgical oncology unit/oncology specialty unit (MSOU) and physician office (MDO). Clinical trials nurses (CTN) and nurses who reported "other" for primary position on the DIF had more positive attitudes compared to staff nurses. Additionally, nurses who reported "other" for primary position had a more positive attitude compared to clinical nurse specialists/nurse practitioners (CNS/NP).

Burnett et al. (2001) reported in their study that research nurses had statistically significantly higher mean scores on their attitude subscale, compared to BMTU/ICU nurses, who had the lowest mean scores on attitudes toward clinical trials. There are several reasons for the differences found in the measurement of oncology nurses' attitudes between Burnett et al. (2001) and this study. First, Burnett et al. (2001) had one demographic question that asked nurses to indicate their main area of work (i.e., inpatient floor [not ICU/BMTU], ICU or BMTU, research nurse, etc.). The demographic independent variables in this study were set a priori and separated work setting and primary position (2 questions on the DIF), which is

identical to the way the 2006 ONS membership application captures this information. Therefore, nurses who indicated they work in BMTU/ICU setting were captured under the primary work setting variable and clinical trial nurses (research nurses) were captured under primary position variable. It is interesting to note that clinical trial nurses in this study had a higher mean score (33.6) than BMTU/ICU nurses (30.7) on the ATCR subscale. This result suggests that clinical trial nurses, in this study, had more positive attitudes toward the benefit of cancer clinical trials compared to BMTU/ICU nurses. The clinical trial nurses, on average, agreed more than BMTU/ICU nurses, that clinical research improves standards of care, patients should participate in research, and would participate in a clinical trial if they had cancer. However, because they were part of two different independent variables, they were not tested against one another with ANOVA. Another reason for the differences in nurses' attitudes in this study compared to results described by Burnett et al. (2001) could be related to the subscales used to measure attitudes toward clinical trials. Burnett et al. (2001) used six items from the NAS to make up their subscale. This study used eight items to measure nurses' attitudes toward clinical trials, the same six items as in Burnett et al. (2001) plus two additional items that factored together to make up the ATCR subscale.

Research Question 2. – What are nurses' perceptions about how effective a research drug or experimental therapy should be before it is offered to patients? Consistent with the study by Burnett et al. (2001) this study found nurses perceived the benefit of an experimental therapy should be high prior to being offered to patients. This perceived benefit exceeded the historical effectiveness of experimental anticancer agents. There have been significant improvements in treatment for patients with advanced cancer over the past 5 years with improvements in overall response rates and survival; yet the rates of complete responses have

been lower than 10% for these palliative treatments (Chu & DeVita, 2005). For earlier stage cancers the absolute improvements in survival are also small. For example, adjuvant chemotherapy for breast cancer achieves absolute 10 year reductions in breast cancer mortality of 5.3% for lymph node positive disease and 12.2% for lymph node negative disease (Early Breast Cancer Trialists' Collaborative Group [EBCTCG], 2005). Additionally, in a pooled analysis of Stage II and III colon cancer patients, overall survival was increased form 64% to 71% with fluorouracil-based chemotherapy, an absolute improvement of 7% (Gill et al., 2004).

Studies evaluating perceptions of the benefits of investigational treatments among patients with cancer also have demonstrated high expectations regarding clinical cancer research (Cassileth et al., 1982; Cheng et al., 2000; Daugherty et al., 1995; Meropol et al., 2003). For example, Meropol et al. (2003) reported that 77% (252 of 338) of patients entering a Phase I cancer clinical trial estimated their chance of benefit being at least 50%. The expectations of nurses in this present study parallel these findings.

In this study, nurses with educational degrees other than master's or doctorate's had significantly higher perceptions of the effectiveness a research drug or experimental treatment should have before being offered to a patient, compared to nurses with master's degrees or higher. Additionally, nurses with fewer than 1–10 years experience as a cancer RN had significantly higher perceptions of benefit compared to nurses with greater than 20 years experience. Nurses grouped by work setting also demonstrated significant differences in their perceptions. Nurses working in MSOU had significantly higher perceptions compared to nurses in HBIC. Nurses in BMTU/ICU and MSOU had significantly higher perceptions compared to nurses in the corporate or industry setting. Nurses who work in MSOU reported higher perceptions compared to nurses who reported "other" for work setting on the DIF.

Finally, staff nurses had significantly higher expectations compared to CNS/NP and nurses who reported "other" for primary position on the DIF.

Why nurses with fewer than 1–10 years experience as a cancer RN had significantly higher perceptions of benefit compared to nurses with greater than 20 years experience is unclear. One explanation may be that the longer an oncology nurse is in practice, the more experience they may have with clinical trials, and, as a result, they have seen experimental therapies produce benefits in the single digits. The investigator was unable to identify other research addressing this issue.

Burnett et al. (2001) reported that research nurses believed a new therapy should have a 25% (median) chance of benefit before entering a clinical trial. For BMTU/ICU nurses, outpatient and inpatient nurses, and operating room nurses, the response median was 50%. The use of reporting the median response in the study by Burnett et al. (2001) makes it difficult to compare to the present study which reported mean response. Mean responses were used because ANOVA tests for significant differences in mean scores between groups as opposed to a median score.

Research Question 3. – What are oncology nurses' perceptions regarding patients' understanding of clinical trials and the treatment regimen? Statistically significant differences were found in the mean scores on the PUK subscale in nurses who worked with clinical trial patients compared to those who did not. The only other group that demonstrated significant differences in their perceptions of patient understanding and knowledge of the treatment regimen was the variable of work setting. Surprisingly, the post hoc test for multiple comparisons failed to demonstrate which of the work settings (nurses who reported being employed in these work settings) had significant differences in their PUK scores. However,

nurses in MDO had the highest mean score compared to all other nurses in this group. This indicates that these nurses had greater agreement with items relating to patients understanding their treatment goals, plan and prognosis, and their wishes being respected by oncologists and nurses compared to other nurses. These findings may reflect MDO nurses' involvement with patient education. In many oncology physicians' offices, the nurse provides additional education related to the treatment goals. Perhaps MDO nurses had more extensive experience observing physicians providing patients with information.

Daugherty et al. (1995) conducted a pilot survey study of 30 cancer patients who had given informed consent to participate in a Phase I clinical trial. Concurrently, the oncologists identified by the surveyed patients as responsible for their care were surveyed as well. According to Daugherty et al. (1995) cancer patients who participate in Phase I clinical trials appear to have an adequate self perceived knowledge of the risks of experimental therapy; however, only a minority has an adequate understanding of the purpose of these trials.

Research Question 4. – What factors do nurses perceive influence a patients' decision to participate in a cancer clinical trial? Nurses' perceptions of patient expectations and reports of patient expectations of the outcomes of a cancer clinical trial are consistent. There was agreement between this study and other studies (Daugherty et al., 1995; Yoder et al., 1997; Meropol et al., 2003) on several factors that nurses believed influenced patient participation in clinical trials. Ninety-three percent of nurses in this study reported that patients entered a clinical trial with a belief of a cure for their cancer. According to published literature, which examined patients' perceptions and motivations to participate in Phase I cancer clinical trials, most patients with cancer reported that their decision to participate in a Phase I clinical trial

was based on the hope of therapeutic benefits (Daugherty et al., 1995; Schuta & Burnett, 2000; Yoder et al., 1997).

Daugherty et al. (1995) conducted a pilot survey study of 30 cancer patients who had given informed consent to participate in a Phase I clinical trial. Concurrently, 18 oncologists identified by the surveyed patients as responsible for their care were surveyed as well. Daugherty et al. (1995) reported that 85% of patients decided to participate in a Phase I clinical trial for reasons of a possible therapeutic benefit.

Consistent with this finding, Yoder et al. (1997) described the expectations and experiences of patients entering Phase I clinical studies. A convenience sample of 37 patients who already had agreed to participate in a Phase I clinical trial were interviewed using structured entry and exit questionnaires. Yoder et al. (1997) reported at the time patients entered a clinical trial, 85% expected a decrease in tumor size. Although these studies did not specifically address the issue of "cure," an expectation of tumor shrinkage and expectation of cure were viewed by patients as an expectation of therapeutic benefit from a clinical trial.

Schuta and Burnett (2000) explored the factors that influenced a patient's decision to participate in a Phase I cancer clinical trial. Two focus groups were conducted with six patients participating in the first and two patients in the second focus group (total $N = 8$). The authors reported that participants in their study expressed hope for a cure and trusting the oncologist's advice as the primary factors for participating in a Phase I clinical trial. The majority (87.5%, $n = 7$) expressed surprise that anyone would participate in an experimental study for altruistic reasons. Moreover, Meropol et al. (2003) described and compared the perceptions of cancer patients and their physicians regarding Phase I clinical trials. Eligible patients had been offered participation in a Phase I trial but had not yet begun treatment. Each patient's physician also

served as a study subject. Forty eight physicians and 128 patients completed surveys with domains including perceptions of potential benefit and harm from treatment (experimental and standard), relative value of quality and length of life, and perceived content of patient-physician consultations. Meropol et al. (2003) reported that 39% of patients entering a Phase I trial believed they would be totally cured; 26% believed their cancer would be reduced, and 30% believed it would be controlled.

Research Question 5. – What are nurses' perceptions of patients' decision-making processes and the desire for information regarding clinical trial participation? The nurses' perceptions of patients' perceptions of the treatment and research process and influences in patient's decisions were measured by the INP subscale. The INP subscale was reverse coded; therefore a lower score indicated more agreement with the items on the subscale. This translates to a lower score indicating more agreement with statements that patients are frightened to ask questions, patients decisions regarding therapy is strongly influenced by their family preferences, and patients are willing to accept side effects for a small benefit in therapy. Two groups emerged as having significant differences in their perceptions, whether nurses work with clinical trial patients (or not), and work setting. Nurses who reported they did not work with clinical trial patients had a significantly lower mean score than nurses who did, and BMTU/ICU nurses had a significantly lower mean score compared to MDO nurses but not to nurses in any other work setting. This indicates that BMTU/ICU nurses agreed more with statements that patients are frightened to ask questions, patients decisions regarding therapy is strongly influenced by their family preferences, and patients are willing to accept side effects for a small benefit in therapy. This may be inherently related to the type of nurse-patient relationship in the BMTU/ICU setting. Patients usually are more gravely ill, and may, be

incapable or less interested in having treatment related knowledge (Ende, Kazis, Ash, & Moskowitz, 1989; Leydon et al., 2000).

Research Question 6. – What are the perceptions of nurses regarding where clinical research should be conducted and the role of oncologists and nurses in clinical trials? The RL subscale evaluated nurses' perceptions of the role oncologists and nurses in clinical research, awareness of patients and location of clinical trials. The RL subscale was reverse coded; therefore a lower score indicated more agreement with items such as oncologists and nurses put too much pressure on patients to participate in research, patients are unaware that their treatment is part of a research protocol and clinical research should only be conducted in cancer centers. Two groups emerged having significant differences in their mean RL scores, nurses working with clinical trial patients (or not) and years of experience as a cancer RN. Nurses who did not work with clinical trial patients had lower mean scores on the RL subscale compared to nurses who do and nurses with less than 1–10 years experience as a cancer RN had significantly lower scores compared to nurses with more experience. The reason why nurses with less than 1–10 years experience and nurses who did not work with clinical trial patients had more agreement with items such as, oncologists and nurses put too much pressure on patients to participate in research, patients are unaware that their treatment is part of a research protocol and clinical research should only be conducted in cancer centers may be explained by the fact that these groups may have less experience with clinical trials and have not experienced patient-oncologist interaction regarding participation in clinical trials.

Research Question 7. Five stepwise multiple regression models were constructed to determine if the independent variables (age, education level, number of years as a cancer RN, whether nurses care for clinical trial patients [or not], work setting, and primary position) serve

as significant predictors related to attitudes and perceptions as measured by the four subscales (ATCR, PUK, INP and RL) and Item 15 on the modified NAS. The variables of primary position, years a cancer RN, work setting, educational level, and whether or not a nurse works with clinical trial patients were significant predictors of attitudes toward cancer clinical trials, perceptions of patients' knowledge of clinical trials, treatment plans, need for information, and perceived benefit about how effective a research drug or experimental therapy should be shown to be before it is offered to patients. However, caution is needed in interpreting the data, as it is difficult to make definitive statements that the predictors identified in this regression analysis serve as great predictors of attitudes and perceptions, since all of the regression models accounted for so little variance. The R^2 values for the five regression models ranged from 0.025 to 0.144, indicating the models accounted for 2.5% to 14.4% of the variance in attitude and perception scores. This indicates there are other variables that predict attitudes and perceptions better than the independent variables chosen for this study, and these variables are unknown.

Burnett et al. (2001) found that practice setting and older age predicted nurses' positive attitudes and perceptions toward clinical trials. However, they also had low R^2 values for their subscales (10%). Older age as a predictor of positive attitudes and perceptions is in contrast to the findings of this study; age was not found to be a predictor for attitudes and perceptions from the multiple regression models constructed for this study. The reason for this difference is unclear and the investigator was unable to identify any other research addressing this issue.

Additional information. The oncology nurses in this study were supportive of the importance of cancer clinical trials improving standards of care in oncology, but not necessarily willing to participate as research subjects if they had cancer. This finding is

consistent with the findings by Burnett et al. (2001) but not to the same magnitude. In both studies greater than 95% of nurses agreed that clinical research improves standards of care in oncology. Burnett et al. (2001) found 56% of nurses agreed that patients should be encouraged to participate in research, while only 35% of nurses stated that they would prefer treatment in a clinical trial. This study found 75% of nurses agreed that patients should be encouraged to participate in research while 51% of nurses stated that they would prefer treatment in a clinical trial. More nurses in this study agreed that patients should be encouraged to participate in research compared to Burnett et al. (2001), 75% vs. 56%. Furthermore, more nurses in this study were willing to participate in a cancer clinical trial if they had cancer compared to Burnett et al. (2001), 51% vs. 35%. These differences may be due to the timing of the data collection; Burnett et al. (2001) collected their data more than 5 years before data collection for this study. Within that time, the NCI has developed and advertised a *Clinical Trials Education Series* (NCI, 2006) and the ONS has updated its position statement on *Cancer Research and Cancer Clinical Trials* three times. A paragraph contained in the position statement relative to this study states: "Barriers to access and environment include system barriers, healthcare barriers, and patient barriers. Modifying attitudes, changing perceptions, and increasing awareness about clinical trials among these groups are paramount to overcoming many of the present barriers" (ONS position statement, 2004, p. 2).

Because of these initiatives, nurses may have a greater awareness of the importance of cancer clinical trial participation. Also, this study collected data from oncology nurses who practice in varied work settings compared to Burnett et al. (2001), they collected data from nurses who only worked in a comprehensive cancer center and this may also be a reason for the differences in how many nurses agree that patients should be encouraged to participate in

research and how many nurses themselves would participate in a clinical trial if they had cancer. Cassileth et al. (1982) found that willingness to participate in research varies depending on whether a subject considers the question of participation as referring to hypothetical individuals rather than themselves.

There were striking differences between the nurses' perceptions of the influence of nurses and oncologists on patients' decisions to enter clinical trials between this study and the only other study to report on oncology nurses attitudes toward cancer clinical trials (Burnett et al., 2001). Almost all the nurses in both studies agreed that nurses respected patient wishes. However, Burnett et al. (2001) reported that 62% of nurses thought that physicians respected patients' wishes, whereas in this study approximately 83% of nurses agreed with this. Also, more than 25% of nurses in the Burnett et al. (2001) study agreed that doctors put too much pressure on patients to participate in clinical trials. In this study less than 10% of nurses agreed with this statement. More than 80% of the nurses in this study perceived that patients were actually well informed when they chose to participate in a clinical trial. This is higher than what has been reported by Burnett et al. (2001) who reported that only 56% of nurses thought that patients were well informed when they chose to participate in a clinical trial. Additionally, Burnett et al. (2001) reported that less than 50% of the nurses they surveyed agreed with the statement "patients understand their prognosis and goals of therapy" (p.1190) whereas, this study found 68% of the nurses agreeing with this statement. Finally, almost one quarter of the nurses surveyed by Burnett et al. (2001) agreed that patients are often unaware that their treatment is part of a research protocol, and approximately 10% of nurses in this study agreed with this statement.

The investigator acknowledges that the responses by the nurses surveyed by Burnett et al. (2001) and the nurses in this study cannot be directly compared. Burnett et al. (2001) surveyed the nurses employed at one comprehensive cancer center. This study surveyed a random sample of oncology nurses who are members of ONS living in the U.S. Also, Burnett et al. (2001) published their data 5 years before this study, as such, attitudes can change over time. Additionally, the NAS had been used in only one prior pilot study (Burnett et al., 2001) and was modified with permission from the authors (see Appendix D). This modification of a relatively new and infrequently used instrument may also explain the low reliability of the INP and RL subscales.

Study Results and Theoretical Framework

The theoretical framework on which this study was based was the Theory of Reasoned Action (TRA) by Ajzen and Fishbein (1980). This study was descriptive and exploratory and was not designed to fully test the TRA. According to the theory, in general, an individual will hold a favorable attitude toward a given behavior if he/she believes that the performance of the behavior leads to mostly positive outcomes. Conversely, if the individual believes that mostly a negative outcome will result from the behavior, he/she will hold a negative attitude toward it.

Concepts of the theory define the nurse's own beliefs, as well as, the perceived beliefs of those groups that are in a position to influence the ideas and actions of the nurse. These beliefs and actions pertain to the nurse's relationship with the patient contemplating enrollment or already enrolled in a cancer clinical trial. Therefore, the combination of the nurse's beliefs and the group belief could lead one to action depending upon which set of beliefs are valued more (or is perceived to lead to a positive outcome) by the nurse, thus forming an attitude on the part of the nurse. Behavior, in turn, is deemed a function of intention.

Therefore, factors associated with intention need to be evaluated to understand and predict behavior (Levin, 1999). One way to evaluate intention is to assess attitudes and perceptions, and this study was an exploration of oncology nurses attitudes and perceptions toward cancer clinical trials. Attitudes need to be evaluated before predictions can be made as to how an individual may behave. One behavior that nurses may perform is to provide education to patients and to clarify information that a patient may not understand. This fact is underscored by the study by Aaronson et al. (1996). The authors evaluated a strategy of providing additional information to patients considering entry into Phase II or III trials at the Netherlands Cancer Institute ($N = 180$). Patients were randomized to the standard consent interview, or the standard interview followed by a telephone call several days later from a clinical trials nurse to further discuss the information provided in the consent interview. This nursing intervention was shown to have a positive effect on cancer patients' awareness of the most important issues surrounding clinical trials in which they are asked to participate.

Overall, oncology nurses in this study had positive attitudes toward cancer clinical trials. Moreover, 98% of nurses in this study agreed that clinical research was important in improving future standards of care. It is impossible to make direct correlations that the oncology nurses surveyed in this study will perform positive behaviors because, in general, they have positive attitudes toward cancer clinical trials. Further research is needed to construct a model or study design that will measure attitudes, the perceived beliefs of significant others, and intentions, and correlate them with a behavior, such as, educational information given by oncology nurses to clinical trial patients.

B. Additional Limitations

After all the data from this study were analyzed there were several additional limitations that became clear.

1. This study used a mailed survey design to collect data from a national sample of oncology nurses. Three hundred and one surveys were used in the analysis equating to 30% of the population sampled. Despite using a stratified random sample design to attempt to obtain a representative sample of oncology nurses who were ONS members, the results may not be representative of entire approximate 32,000 members of ONS. Thus, an inherent limitation with mailed surveys is nonresponse bias (Dillman, 2000). As such, nonresponse bias could have reduced the random probability sample of this study to essentially a convenience sample and consequently, the conclusions become much weaker. It is unknown if nonresponders would have answered the items on the NAS differently from responders.

2. The population studied was a defined group of oncology nurses who are ONS members who allowed their names and addresses to be made public. Their attitudes and perceptions may not necessarily parallel those of nononcology nurses, oncology nurses not members of ONS, or ONS members who did not allow their contact information to be made public. Additionally, geographic diversity is unknown from this population of nurses, and there may have been differences in patterns of care of cancer patients based on where they live (Gregorio et al., 2001; Hanlan et al., 1995). There are standards of care that have been defined by cancer research leaders; however, there remains a "gap" between the recommended standards and oncology care delivered by community oncologists (Love, 2005). Therefore, nurses from one part of the country may approach cancer clinical trials differently than nurses in another part of the country. Geographic information was not captured on the DIF.

3. The modified NAS may have been a limitation in the conclusion drawn from the data analysis. This is based upon the low coefficient of determination (R^2) found in this study and its ability to define variables (groups of nurses) that predict positive attitudes toward clinical trials. There may be other variables that were not captured on the DIF that serve as better predictors of attitudes and perceptions, such as geographic location of employment. Along the same line, the DIF questions for work setting and primary position are identical to the ONS membership application, and there was no way to differentiate between nurses working in a comprehensive cancer center and nurses in other settings. In retrospect, the investigator could have included a yes/no question on the DIF that asked "Do you work in a comprehensive cancer center?"

4. The original NAS used two subscales to measure attitudes and perceptions and was designed to measure two constructs (attitudes and perceptions) and used one 6-item subscale to measure attitudes and another 6- item subscale to measure perceptions. In retrospect, it may have been more appropriate to perform a factor analysis to evaluate two subscales. This is supported by the fact that the INP and RL subscales, determined by the factor analysis had low Cronbach's alpha.

5. The TRA attempts to predict human behavior, based on concepts of personal beliefs, which lead to attitudes toward the behavior, and perceived beliefs of others, which lead to subjective norms. The attitudes and subjective norms lead to behavioral intention and then finally to performing a behavior. This study was based on one side of the TRA and addressed nurses' attitudes only. It did not take into account the nurses perceived beliefs of others and subjective norms

6. Finally, the inclusion of nurses from the corporate/industry setting may have confounded the generalizability of the results, because it is hypothesized that this group works in the research field and may have very strong positive attitudes toward clinical trials.

C. Implications

Oncology nurses play a key role in the clinical and research settings by serving as direct caregivers, patient advocates, educators, counselors, as well as facilitators of clinical trials. As such, nurses have a major role in cancer clinical trials, yet not much research into their attitudes and perceptions has been undertaken. Nurses' attitudes and perceptions regarding cancer clinical trials may ultimately dictate their behaviors towards patients enrolled in or contemplating enrollment in such trials. By investigating oncology nurses attitudes and perceptions toward cancer clinical trials this study may begin to assess the behavior of oncology nurses towards clinical trial patients. These behaviors can include direct patient care, coordination of care, patent education, and patient advocacy. The findings of this study have implications for nursing education, nursing practice, and the conduct of clinical trials. For example: In-patient nurses (BMTU/ICU & MSOU) compared to MDO & HBIC were less likely to agree that patient understood their management plan, understood their prognosis and therapy goals, and patients are well informed when they choose to participate in a clinical trial. Patient care and the conduct of clinical trials may be improved if these concerns are reconciled.

D. Recommendations for Further Research

Based on the results obtained from this study the investigator recommends the following areas that need to have further exploration.

The entire modified NAS had high internal consistency, with a Cronbach's alpha of 0.72; however, the Cronbach's alpha of RL and INP subscales were 0.47 and 0.56,

respectively, indicating that the subscales had fair to poor reliability. Because of this, further research is needed to develop an improved instrument to measure oncology nurses' attitudes and perceptions of the informational needs of patients involved in clinical trials. One option is to conduct a qualitative study using focus groups for the purpose of exploring common themes related to nurses' attitudes and perceptions toward cancer clinical trials. It might be advantageous to use focus groups to collect these data using nurses from the ONS clinical trial nurses special interest group (SIG) and from the pharmaceutical/industry nursing (PIN) SIG. The reason for inclusion of this later group is this study revealed that nurses in the CI setting and CTN had more positive attitudes toward cancer clinical trials and more realistic expectations of the benefit of cancer therapy offered as research. Nurses who are members of the clinical trials SIG and PIN SIG most likely represent CI nurses from this study. From this qualitative study there may be items that are common to themes found on the modified NAS; these items could then be incorporated into the NAS. The NAS could continue to be modified and pilot tested for measuring nurses' attitudes and perceptions.

Once an instrument measuring nurses' attitudes and perceptions has been refined, a further recommendation would be to construct a model that will measure attitudes, the perceived beliefs of significant others, and intentions, then correlate them with a behavior, such as, educational information given by oncology nurses to clinical trial patients, to formally test the Theory of Reasoned Action. Finally, an intervention study could be undertaken looking at providing educational strategies that may change the attitudes and behaviors of oncology nurses working with clinical trial patients. This may help with increasing the number of patients into clinical trials.

E. Conclusion

This study was only the second and largest study to date exploring oncology nurses' attitudes toward clinical trials and their perceptions of patient understanding and knowledge. This is underscored by the fact that a systematic review of the relevant literature from 1996 to 2006, relating to the barriers, modifiers and benefits involved in participating in randomized controlled trials of cancer therapies as perceived by healthcare providers and patients, was undertaken by the Center for Reviews and Dissemination (CRD), University of York (Fayter, McDaid, Ritchie, Stirk, & Eastwood, 2006). In their review, the authors found 17 studies examining attitudes of health professionals to participation in cancer clinical trials. However, there was only one study which explored the views of oncology nurses, and that study was by Burnett, et al. (2001).

Despite high internal consistency of the entire modified NAS, the four subscales derived from the factor analysis revealed varying degrees of internal consistency. This study discovered significant predictors to attitudes and perceptions; however, all R^2 (coefficient of determination) values were very low, indicating that there were some other unknown variables that could be better predictors than the ones used in this study. On average, oncology nurses had positive attitudes towards cancer clinical trials. However, statistically significant differences were found between nurses grouped by primary work setting and primary position. Additionally, as a whole, these nurses perceived that patients have enough information to make decisions regarding clinical trial participation and they somewhat disagreed that clinical research should be conducted only in cancer centers, oncologists and nurses put too much pressure on patients to participate in clinical trials, and patients are often unaware that their treatment is part of a research protocol. Significant differences in these perceptions were found

between the following variables: primary work setting, number of years in cancer nursing, and whether or not a nurse works with clinical trial patients. Consistent with prior research, oncology nurses perceived that experimental cancer treatments should have a large benefit before being offered to patients. Moreover, there were statistically significant differences in this perceived benefit between the nurses grouped by number of years in cancer nursing, primary work setting and highest education level. More research is needed to explore the reasons for these differences in attitudes and perceptions. Finally, more research is needed to truly evaluate the TRA as a model of educational behaviors nurses use providing education to patients involved with cancer clinical trials.

References

Aaronson, N., Visser-Pol, E. Leenhouts, G. H., Muller, M. J., van der Schot, A. C., van Dam, F. S., et al. (1996). Telephone nursing intervention improves the effectiveness of the informed consent process in cancer clinical trials. *Journal of Clinical Oncology*, *14*, 984–996.

Ajzen, I. (1985). From intentions to actions: A theory of planned behavior. In J. Kuhl & J. Beckman (Eds.), *Action-control: From cognition to behavior* (pp. 11–39). Heidelberg: Springer.

Ajzen, I. (2001). Nature and operation of attitudes. *Annual Review in Psychology, 52*, 27–58.

Ajzen, I., & Fishbein, M. (1980). *Understanding attitudes and predicting social behavior*, Englewood Cliffs, NJ: Prentice-Hall.

Ajzen, I., & Fishbein, M. (2000). Attitudes and the attitude-behavior relation: Reasoned and automatic processes. In W. Stroebe & M. Hewstone (Eds.), *European review of social psychology* (pp. 75-100). Chichester, England: Wiley.

Allport, G. W. (1935). Attitudes. In C. Murchinson (Ed.), *A handbook of social psychology.* Worchester MA: Clark University Press.

Ary, D., Jacobs, L., & Razavieh, A. (2002). *Introduction to research in education* (6th ed.).Belmont, CA: Wadsworth Thomson Learning.

Babbie, E. (1990). *Survey research methods* (2nd ed.). Belmont, CA: Wadsworth.

Barrett, R. (2002). A nurses' primer on recruiting participants for clinical trials. *Oncology Nursing Forum*, *29*, 1091–1096.

Bavier, A. R. (2003). Types of disclosure discussions between oncology nurses and

patients/families: An exploratory study. Unpublished doctoral dissertation.

Beauchamp, T. L., & Childress, J. F. (2001). *Principles of biomedical ethics*. Oxford: Oxford University Press.

Becker, M. H., Radius, S. M., & Rosenstock, I. M. (1978). Compliance with a medical regimen for asthma: A test of the health belief model. *Public Health Reports, 93*, 268–277.

Beecher, H. K. (1966). Ethics and clinical research, *New England Journal of Medicine 274*, 1354–1360.

Berry, D. L., Dodd, M. J., Hinds, P. S., & Ferrell, B. R. (1996). Ethical issues informed consent: Process and clinical issues. *Oncology Nursing Forum*, *23*, 507–512.

Bland, J. M., & Altman, D. G. (1997). Statistics notes: Cronbach's alpha. *British Medica Journal*, *314*, 572.

Bok, S. (1995). Shading the truth in informed consent for clinical research. *Kennedy Institute of Ethics Journal*, *5*, 1–17.

Bourque, L. B., & Fielder, E. P. (2003). *How to conduct self-administered and mail surveys* (2nd ed.). Thousand Oaks, CA: Sage Publications.

Brace, N., Kemp, R., & Snelgar, R. (2006). *SPSS for psychologists* (3rd ed.). Mahwah, NJ: Lawrence Erlbaum Associates, Inc.

Brown, C. G. (2003). Male oncology nurses share commitment, dedication, and love of the profession. *ONS News*, *18*, 1–5.

Buerhaus, P. I. (2002). Shortages of hospital registered nurses: Causes and perspectives on Public and private sector actions. *Nursing Outlook*, *50*, 4–6.

Burjorian, G. A. (1988). Clinical trials: Patient issues in the decision-making process.

Oncology Nursing Forum, *15*, 779–783.

Burnett, C. B, Koczwara, B., Pixley, L, Blumenson, L. E., Hwang, Y. T., & Meropol, N. J. (2001). Nurses' attitudes toward clinical trials at a comprehensive cancer center. *Oncology Nursing Forum, 28*, 1187–1192.

Cassidy, J., & MacFarlane, D. (1991). The role of the nurse in clinical cancer research. *Cancer Nursing*, *14*, 124–131.

Cassileth, B. R., Lusk, E. J., Miller, D. S., & Hurwitz, S. (1982). Attitudes towards clinical trials among patients and the public. *JAMA*, *248*, 968–970.

Cassileth B. R., Zupkis R. V., Sutton-Smith, K., & March, V. (1980). Information and participation preferences among cancer patients. *Annals of Internal Medicine*, *92*, 832–836.

Chang, A. (2004). Nurses' perceptions of phase I clinical trials in oncology: A review of the literature. *Journal of Pediatric Oncology Nursing*, *21*, 343–349.

Cheng, J. D., Hitt, J., Koczwara, B., Schulman, K. A., Burnett, C., Gaskin, D. J., et al. (2000).Impact of quality of life on patient expectations regarding phase I clinical trials. *Journal of Clinical Oncology*, *18*, 421–428.

Clarke, K. E., & Aish, A. (2002). An exploration of health beliefs and attitudes of smokers with vascular disease who participate in or decline a smoking cessation program. *Journal of Vascular Nursing*, *20*, 96–105.

Comis, R. L., Miller, J. D., Aldigé, C. R., Krebs, L., & Stoval, E. (2003). Public attitudes Toward participation in cancer clinical trials. *Journal of Clinical Oncology*, *21*, 830–835.

Cox, K. (1999). Researching research: Patients' experiences of participation in phase I

and II anti-cancer drug trials. *European Journal of Oncology Nursing*, *3*,143–152.

Cox, K., & Avis, M. (1996). Psychosocial aspects of participation in early anticancer drug trials. *Cancer Nursing*, *19*, 177–186.

Cronbach, L. J. (1951). Coefficient alpha and the internal structure of tests. *Psychometrika*, *16*, 297–335.

Daugherty, C., Ratain, M. J., Grochowski, E., Stocking, C., Kodish, E., Mick, R., & Siegler, M. (1995). Perceptions of cancer patients and their physicians involved in phase I trials. *Journal of Clinical Oncology*, *13*, 1062–1072.

Davis, S. W., Nealon, E. O., & Stone, J. C. (1993). Evaluation of the National Cancer Institute's clinical trials booklet. *Journal of the National Cancer Institute Monographs*, *14*, 139–145.

Degner, L. F., Kristjanson, L. J., Bowman, D., Sloan, J. A., Carriere, K. C., O'Neil, J., et al.(1997) Information needs and decisional preferences in women with breast cancer. *JAMA, 277*, 1485–1492.

Degner, L. F., & Sloan, J. A. (1992). Decision making during serious illness: What role do patients really want to play? *Journal of Clinical Epidemiology, 45*, 941–950.

DeVellis, R. F. (2003). *Scale development: Theory and Applications* (2nd ed.). Thousand Oaks, CA: Sage Publications, Inc.

DiClemente, C. C. (1997). *Beyond the stages of change: Applications to health behavior change*. San Francisco, CA: Society for Behavioral Medicine.

Dillman, D. A. (2000). *Mail and Internet surveys: The tailored design method*. New York: John Wiley & Sons.

Dunkle, S. E., & Hyde, R. S. (1995). Predictors and subsequent decisions of physical therapy and nursing students to work with geriatric clients: An application of the theory of reasoned action. *Physical Therapy*, *75*, 614–620.

Early Breast Cancer Trialists' Collaborative Group (EBCTCG). (2005). Effects of chemotherapy and hormonal therapy for early breast cancer on recurrence and 15 year survival: An overview of the randomized trials. *Lancet*, 365, 1687-1717.

Ellis, P. M., Bulow, P. N., Tattersall, M. H. N., Dunn, S. M., & Houssami, N. (2001). Randomized clinical trials in oncology: Understanding and attitudes predict willingness to participate. *Journal of Clinical Oncology*, *19*, 3554–3561.

Ehrenberger, H. E., & Lillington, L. (2004). Development of a measure to delineate the clinical trials nursing role. *Oncology Nursing Forum*, *31*, 64–68.

Ende, J., Kazis, L., Ash, A., & Moskowitz, M.A. (1989). Measuring patients' desire for autonomy: Decision-making and information-seeking preferences among medical patients. *Journal of General Internal Medicine*, *4,* 23-30.

Engelking, C. (1992). Clinical trials: Impact evaluation and implementation considerations. *Seminars in Oncology Nursing*, *8*, 148–155.

Fayter, D., McDaid, C., Ritchie, G., Stirk, L., & Eastwood, A. (2006). Systematic review of barriers, modifiers and benefits involved in participation in cancer clinical trials. *Center for Reviews and Dissemination, University of York*. Retrieved March 15, 2007, from http://www.york.ac.uk/inst/crd/pdf/report31.pdf

Fazio, R. H., & Roskos-Ewoldsen, D. R. (1994). Acting as we feel: When and how attitudes guide behavior. In S. Shavitt & T. C. Brock (Eds.), *Persuasion: Psychological insights and perspectives* (pp. 41-62). Needham Heights, MA: Allyn & Bacon.

Finn, R. (1999). *Cancer Clinical Trials: Experimental Treatments & How They Can Help You*. Sebastopol, CA: O'Reilly & Associates, Inc.

Fleury, J. (1992). The application of motivational theory to cardiovascular risk reduction. *Image: Journal if Nursing Scholarship*, *24*, 229–239.

Georgaki, S., Kalaidopoulou, O., Liarmakopoulos, I., & Mystakidou, K. (2002). Nurses Attitudes toward truthful communication with patients with cancer. *Cancer Nursing*, *25*, 436–441.

Gill, S., Loprinzi, C. F., Sargent, D. J., Thomé, S. D., Alberts, S. R., Haller, D. G., et al. (2004). Pooled analysis of fluorouracil-based adjuvant therapy for stage II and III colon cancer: Who benefits and how much. *Journal of Clinical Oncology*, *22*, 1797–1806.

Gonot, P. J. (1989). Imogene King's conceptual framework of nursing. In J. J. Fitzpatrick & A. L. Whall (Eds.), *Conceptual Models of Nursing: Analysis and Application* (2nd ed., pp. 271–283). Norwalk, CT: Appleton and Lange.

Gorsuch, R. L. (1983). *Factor analysis* (2nd ed.). Hillsdale, NJ: Lawrence Erlbaum Associates.

Grady, C. (1991). Ethical issues in clinical trials. *Seminars in Oncology Nursing, 7*(4), 288–296.

Grady, D., Cummings, S. R., & Hulley, S. B. (2001). Designing an experiment: Clinical trials II. In S. B. Hulley, S. R. Cummings, W. S. Browner, D. Grady, N. Hearst, & T. B. Newman, *Designing clinical research: An epidemiologic approach* (2nd ed., pp. 157–174). Philadelphia: Lippincott Williams & Wilkins.

Gregorio, D. I., Kulldorff, M., Barry, L., Samocuik, H., & Zarfos, K. (2001). Geographical differences in primary therapy for early stage breast cancer. *Annals of Surgical Oncology*, *8*, 844–849.

Grunfeld, E., Zitelsberger, L., Coristine, M., & Aspelend, F. (2002). Barriers and facilitators to enrollment in cancer clinical trials. *Cancer*, *95*, 1577–1583.

Hanlon, L., Brawley, O., Pommerenke, F., Wali, P., & Kramer, B. (1995). Geographic, age, racial, variation in the treatment of local/regional carcinoma of the prostate. *Journal of Clinical Oncology*, *13*, 93–100.

Hatcher, L. (1994). *A step-by-step approach to using the SAS® system for factor analysis and structural equation modeling*. Cary, NC: SAS Institute.

Hazelton, J. (1991). The role of the nurse in phase I clinical trials. *Journal of Pediatric Oncology Nursing*, *8*, 43–45.

Horstmann, E., McCabe, M. S., Grochow, L., Yamamoto, S., Rubinstein, L., Budd, T., et al. (2005). Risks and benefits of phase I oncology trials, 1991 through 2002. *New England Journal of Medicine*, *352*, 895–904.

Hubbard, S. (1985). Principles of clinical research. In B. L. Johnson & J. Gross (Eds.), *Handbook of oncology nursing* (pp. 67–90). New York: Wiley.

Husted, G. L., & Husted, J. H. (2001). *Ethical decision making in nursing and healthcare: The symphonological approach* (3rd ed). New York: Springer Publishing Company.

Hutcheson, G., & Sofroniou, N. (1999). *The multivariate social scientist: Introductory statistics using generalized linear models*. Thousand Oaks, CA: Sage Publications.

Jemal, A., Siegel, R., Ward, E., Murray, T., Xu, J., Smigal, C., et al. (2006). Cancer statistics, 2006. *CA: A Cancer Journal for Clinicians*, *56*, 106–130.

Jenkins, J., & Hubbard, S. (1991). History of clinical trials. *Seminars in Oncology Nursing*, *7*, 228–234.

Jerewski, M. A., Brown, J. K., Wu, Y. W. B., Meeker, M. A., Feng, J. Y., & Bu, X. (2005). Oncology nurses' knowledge, attitudes, and experiences regarding advance directives. *Oncology Nursing Forum*, 32, 319–327.

Johansen, M. A., Mayer, D. K., & Hoover, H. C. (1991). Obstacles to implementing cancer clinical trials. *Seminars in Oncology Nursing*, *7*, 260–267.

Joshi, T. G., & Ehrenberger, H. E. (2001). Cancer clinical trials in the new millennium: Novel challenges and opportunities for oncology nursing. *Clinical Journal of Oncology Nursing*, *5*, 147–152.

Keeney, R. L. (1992). *Value-focused thinking: A path to creative decision making*. Cambridge, MA: Harvard University Press.

Keppel, G., & Wickens, T. D. (2002). *Design and analysis: A researcher's handbook* (4th ed.). Englewood Cliffs, NJ: Prentice-Hall.

King, I. M. (1981). *A theory for nursing.* New York: Wiley.

Kleier, J. A. (2004). Nurse practitioners' behavior regarding teaching testicular self-examination. *Journal of the American Academy of Nurse Practitioners*, *16*, 206–212.

Krisjansdottir, G. (1992). Empathy: A therapeutic phenomenon in nursing care. *Journal of Clinical Nursing*, *1*, 131–140.

Krosnick, J. A. (1999). Survey research. *Annual Reviews of Psychology*, *50*, 537–567.

LaPiere, R. T. (1934). Attitudes vs. actions. *Social Forces*, *13*, 230–237.

Lara, P. N., Higdon, R., Lim, N., Kwan, K., Tanaka, M., Lau, D. H., et al. (2001). Prospective evaluation of cancer clinical trial accrual patterns: identifying potential barriers to enrolment. *Journal of Clinical Oncology*, *19*, 1728–1733.

Levin, P. F. (1999). Test of Fishbein and Ajzen models as predictors of health care workers' glove use. *Research in Nursing and Health, 22*, 295–307.

Liaschenko, J., & DeBruin D. (2003). The role of nurses in ensuring the responsible conduct of clinical trials. *Minnesota Medicine*, *86*, 35–36.

Llewellyn-Thomas, H. A., McGreal, M. J., & Theil, E. C. (1995). Cancer patients decision-making and trial entry preferences—the effects of framing information about short-term toxicity and long-term survival. *Medical Decision Making*, *15*, 4–12.

Love, N. (Ed.). (2005). Management of breast cancer in the adjuvant and metastatic settings. *Patterns of Care in Medical Oncology*, *2*, 3–50.

Leydon, G.M., Boulton, M., Moynihan, C., Jones, A., Mossman, J., Boudioni, M, et al. (2000). Cancer patients' information needs and information seeking behavior: In Depth interview study. *British Medical Journal, 320*, 909-913.

MacCallum, R. C., Widaman, K. F., Preacher, K. J., & Hong, S. (2001). Sample size in factoranalysis: The role of model error. *Multivariate Behavioral Research*, *36*, 611–637.

McEnvoy, M. D., Cannon, L., & MacDermott, M. L. (1991). The professional role for nurses in clinical trials. *Seminars in Oncology Nursing*, *7*, 268–274.

McGahee, T. W., Kemp, V., & Tingen, M. (2000). A theoretical model for smoking prevention studies in preteen children. *Pediatric Nursing*, *26*, 135–138.

Meropol, N. J., Weinfurt, K. P., Burnett, C. B., Balshem, A., Benson, A. B., Castel, L., et al. (2003). Perceptions of patients and physicians regarding phase I cancer clinical trials: Implications for physician-patient communication. *Journal of Clinical Oncology*, *21*, 2589–2596.

Miller, M. B., (1995). Coefficient alpha: A basic introduction from the perspectives of classical test theory and structural equation modeling. *Structural Equation Modeling*, *2*, 255–273

Miller, P., Johnson, N., Garrett, M. J., Wikoff, R., & McMahon, M. (1982). Health beliefs of and adherence to the medical regimen by patients with ischemic heart disease. *Heart & Lung*, *11*, 332–340.

Miller, P., Wikoff, R., & Hiatt, A. (1992). Fishbeins's model of reasoned action and compliance behavior of hypertensive patients. *Nursing Research, 41*, 104–109.

Miller, P., Wikoff, R., McMahon, M., Garrett, M. J., & Johnson, N. (1982). Development of a health attitude scale. *Nursing Research*, *31*, 132–136.

Minnick, A. F. (1980). Patient teaching by registered nurses: A study of the relationship beliefs, intentions, and health locus of control with teaching behavior. (Doctoral Dissertation, Northwestern University, 1980). *Dissertation Abstracts International, 41*(09A), 750.

Moore, S. (2001). A need to try everything: Patient participation in phase I trials. *Journal of Advanced Nursing*, *33*, 738–747

Morrison, D. F. (1990). *Multivariate statistical methods*. New York: McGraw-Hill.

Morrow, G. R., Hickok, J. T., & Burish, T. G. (1994). Behavioral aspects of clinical trials: An integrated framework from behavior theory. *Cancer*, *74*, 2676–2682.

National Cancer Institute (2006). *Clinical trials education series.* Retrieved February, 20, 2007, from http://www.cancer.gov/clinicaltrials/learning/clinical-trials-education-series.

National Cancer Institute (2006). *Dictionary of cancer terms*. Retrieved March 13, 2006, from http://www.cancer.gov/templates/db_alpha.aspx?expand=C

National Institutes of Health (1979). Office of Human Subject Research. *The Belmont Report*. Retrieved September 22, 2005, from http://ohsr.od.nih.gov /guidelines/belmont.html.

Nealon, E., Blumberg, B., & Brown, B. (1985). What do patients know about clinical trials? *American Journal of Nursing*, *85*, 807–810.

Nunnally, J. C., & Bernstein, I. H. (1994). *Psychometric Theory* (3rd ed.). New York: McGraw- Hill.

Nuremberg Military Tribunal (1949). *Trials of war criminals before the Nuremberg military tribunals under Control Council Law No. 10*, Vol. 2, Nuremberg, October 1946 to April 1949. Washington, DC: US Government Printing Office.

Ocker, B. M., & Pawlik-Plank, D. M. (2000). The research nurse role in a clinic-based oncology research setting. *Cancer Nursing*, *23*, 286–292.

Office of Behavioral and Social Sciences Research. (2003). Retrieved July 2, 2004, from http://obssr.od.nih.gov/IRB/whatis.htm.

Oncology Nursing Society. (1998). Cancer research and cancer clinical trials [Position statement]. *Oncology Nursing Forum*, *25*, 973–974.

Oncology Nursing Society. (2004). *Statement on the scope and standards of oncology nursing practice*. Pittsburgh, PA: ONS Publishing.

Partridge, A. H., Hackett, N., Blood, E., Gelman, R., Joffe, S., Bauer-Wu, S., et al. (2004).Oncology physician and nurse practices and attitudes regarding offering clinical trial results to study participants. *Journal of the National Cancer Institute*, *96*, 629–632.

Petty, R. E., Wegener, D. T., & Fabrigar, L. R. (1997). Attitudes and attitude change. *Annual Review of Psychology*, *48*, 609–647.

Polit, D. F., & Beck, C. T. (2004). *Nursing research: Principles and methods* (7th ed.). Philadelphia: Lippincott Williams & Wilkins.

Poss, J. E. (1999). Developing an instrument to study the tuberculosis screening behaviors of Mexican migrant farmworkers. *Journal of Transcultural Nursing*, *10*, 306–319.

Poss, J. E. (2000). Factors associated with participation by Mexican migrant farmworkers in a tuberculosis screening program. *Nursing Research, 49*, 20–28.

Poss, J. E. (2001). Developing a new model for cross-cultural research: Synthesizing the Health Belief Model and the Theory of Reasoned Action. *Advances in Nursing Science*, *23*, 1–15.

Public Law 93–348 National Research Act of 1974. Retrieved July 1, 2004, from http://www.fas.harvard.edu/~research/PL93–348.html.

Rajagopal, S., Goodman, P. J., & Tannock, I. F. (1994). Adjuvant chemotherapy for breast cancer: discordance between physicians' perception of benefit and the results of clinical trials. *Journal of Clinical Oncology*, *12*, 1296–1304.

Renfroe, D. H., O'Sullivan, P. S., & Mcgee, G. W. (1990). The relationship of attitude, subjective norm, and behavioral intent to the documentation behavior of nurses. *Scholarly Inquiry for Nursing Practice, 4*, 61–64.

Ries, L. A. G., Smith, M. A., Gurney, J. G, Linet, M., Tamra, T., Young, J. L., Bunin, G. R. (Eds.). (1999). *Cancer Incidence and Survival among Children and Adolescents: United States SEER Program 1975–1995*, National Cancer Institute, SEER Program. NIH Pub. No. 99–4649. Bethesda, MD.

Roberts, T. G., Jr., Goulart, B. H., Squitieri, L., Stallings, S. C., Halpern, E. F., Chabner, B. A., et al. (2004). Trends in the risks and benefits to patients with cancer participating in phase I clinical trials. *Journal of the American Medical Association*, *292*, 2130–2140.

Rosenstock, I. M., Strecher, V. J., & Becker, M. H. (1994). The health belief model and HIV risk behavior change. In R. J. DiClemente & J. L. Peterson (Eds.), *Preventing AIDS: Theories and Methods of Behavioral Interventions* (pp. 5–24). New York: Plenum Press.

Rosse, P. A., & Krebs, L. U. (1999). The nurse's role in the informed consent process. *Seminars in Oncology Nursing*, *15*, 116–123.

Sadler, G. R., Lantz, J. M., Fullerton, J. T., & Dault, Y. (1999). Nurses' unique role in randomized clinical trials. *Journal of Professional Nursing*, *15*, 106–115.

Sanbomatsu, D. M., & Fazio, R. H. (1990). The role of attitudes in memory-based decision making. *Journal of Personality and Social Psychology*, *59*, 614–622.

Santos, J. R. A. (1999). Cronbach's Alpha: A tool for assessing the reliability of scales. *Journal of Extension*, 37. Retrieved February 11, 2006, from http://www.joe.org/joe/1999april/index.html.

Sarna, L., Wewers, M. E., Brown, J. K., Lillington, L., & Brecht, M. L. (2001). Barriers to tobacco cessation in clinical practice: report from a National Survey of Oncology Nurses. *Nursing Outlook, 49*, 166–172.

Sateren, W. B., Trimble, E. L., Abrams, J., Brawley, O., Breen, N., Ford, L., et al. (2002).

How sociodemographics, presence of oncology specialists, and hospital cancer programs affect accrual to cancer treatment trials. *Journal of Clinical Onocology*, *20*, 2109–2117.

Schaefer, D. R., & Dillman, D. A. (1998). Development of a standard e-mail methodology: Results of an experiment. *Public Opinion Quarterly*, *62*, 378–397.

Schutta, K. M., & Burnett, C. B. (2000). Factors that influence a patient's decision to Participate in a phase I cancer clinical trial. *Oncology Nursing Forum*, *27*, 1435–1438.

Seaman, M. A., Levin, K. R., & Serlin, R. C. (1991). New developments in pairwise multiple comparisons: Some powerful and practicable procedures. *Psychological Bulletin*, *110*, 577–586.

Simes, R. J., Tattersall, M. H. N., Coates, A. S., Raghavan, D., Solomon, H. J., & Smartt, H. (1986). Randomized comparison of procedures for obtaining informed consent in clinical trials of treatment of cancer. *British Medical Journal*, *293*, 1065–1068.

Slevin, M. L., Stubbs, L., Plant, H. J., Wilson, P., Gregory, W. M., Armes, P. J., et al. (1990). Attitudes to chemotherapy: Comparing views of patients with cancer with those of doctors, nurses, and general public. *British Medical Journal*, *300*, 1458–1460.

Stevens, J. P. (2002). *Applied multivariate statistics for the social sciences* (4th ed.). Mahwah, NJ: Lawrence Erlbaum Associates, Inc.

Strader, M. K., & Beaman, M. L. (1991). Comparison of selected college students' and sexually transmitted disease clinic patients' knowledge about AIDS, risk behavior and beliefs about condom use. *Journal of Advanced Nursing, 16*, 584–590.

Stuppy, D. J., Armstrong, M. L., & Casals-Ariet, C. (1998). Attitudes of health care

Providers and students towards tattooed people. *Journal of Advanced Nursing*, *27*, 1165–1170.

Taylor, E. J., Highfield, M., & Amenta, M. (1994). Attitudes and beliefs regarding spiritual care. A survey of cancer nurses. *Cancer Nursing, 17*(6), 479–487.

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979, April 18). *The Belmont report*. Retrieved July 2, 2004, from http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm.

Volker, D. L. (2001). Oncology nurses' experiences with requests for assisted dying from terminally ill patients with cancer. *Oncology Nursing Forum, 28*(1), 39–49.

Yoder, L. H., O'Rourke, T. J., Etnyre, A., Spears, D. T., & Brown, T. D. (1997). Expectations and experiences of patients with cancer participating in phase I clinical trials. *Oncology Nursing Forum*, *24,* 891–896.

Waltz, C. F., & Bausell, R. B. (1981). *Nursing research: Design, statistics and computer analysis*. Philadelphia: F.A. Davis.

Waltz, C. F., Strickland, O. L., & Lenz, E. R. (1991). *Measurement in nursing research*. Philadelphia: F.A. Davis.

Winslow, G. R. (1984). From loyalty to advocacy: A new metaphor for nursing. *Hastings Center Report*, *14*, 32–40.

Zigmond A. S., & Snaith, R. P. (1983). The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica***,** *67*, 361–370

Appendices

Appendix A

Survey of Nurses Attitudes Toward Cancer Clinical Trials v.4
Modified with permission (Burnett et al. 2001).

I. Clinical research using patients as research subjects.

For the following statements please mark the category closest to your opinion.

	Strongly disagree 1	***Somewhat disagree*** 2	***Neutral*** 3	***Somewhat agree*** 4	***Strongly agree*** 5
1. Conducting patient research is an important role of oncologists.	☐	☐	☐	☐	☐
2. Clinical research should be conducted only in cancer centers/institutes.	☐	☐	☐	☐	☐
3. It is appropriate for oncologists to invite their clinic patients to be subjects in trials that they conduct.	☐	☐	☐	☐	☐
4. It is appropriate for oncologists to be the person consenting research subjects for their trials, if the research subjects are their own clinic patients.	☐	☐	☐	☐	☐
5. Clinical research improves patient care for the patient involved.	☐	☐	☐	☐	☐
6. Hospitals that conduct clinical research have better standards of care than hospitals that do not.	☐	☐	☐	☐	☐
7. Clinical research in oncology is important in improving future standards of care in oncology.	☐	☐	☐	☐	☐
8. Patients should be encouraged to participate in research.	☐	☐	☐	☐	☐
9. Oncologists put too much pressure on patients to participate in clinical trials.	☐	☐	☐	☐	☐
10. Nurses put too much pressure on patients to participate in clinical trials.	☐	☐	☐	☐	☐

	Strongly disagree	*Somewhat disagree*	*Neutral*	*Somewhat agree*	*Strongly agree*
	1	2	3	4	5
11. If I had cancer, I would prefer to be treated as part of a clinical trial.	☐	☐	☐	☐	☐
	1	2	3	4	5
12. In general, patients are well informed when they choose to participate in a clinical trial.	☐	☐	☐	☐	☐
	1	2	3	4	5
13. Patients are often unaware that their treatment is part of a research protocol.	☐	☐	☐	☐	☐
14. Patients participate in research because of:					
	1	2	3	4	5
A. wish for cure	☐	☐	☐	☐	☐
	1	2	3	4	5
B. wish for improved quality of life (i.e., symptom control)	☐	☐	☐	☐	☐
	1	2	3	4	5
C. hope for better medical care	☐	☐	☐	☐	☐
	1	2	3	4	5
D. desire to please their oncologist	☐	☐	☐	☐	☐
	1	2	3	4	5
E. pressure from oncologist	☐	☐	☐	☐	☐
	1	2	3	4	5
F. wish to help others	☐	☐	☐	☐	☐
	1	2	3	4	5
G. family wishes	☐	☐	☐	☐	☐
	1	2	3	4	5
H. no other option	☐	☐	☐	☐	☐
	1	2	3	4	5
I. inability to accept that nothing else can be done	☐	☐	☐	☐	☐
	1	2	3	4	5
J. inability to accept death	☐	☐	☐	☐	☐

15. In your opinion, in order for a research drug or experimental therapy to be offered to patients, it should have at least _____% chance of producing a desired effect (*please insert a number*)

II. Patient care and communication

For the following statements please mark the category closest to your opinion.

	Strongly disagree	***Somewhat disagree***	***Neutral***	***Somewhat agree***	***Strongly agree***
	1	2	3	4	5
16. Patients' wishes regarding treatment are respected by nurses.	☐	☐	☐	☐	☐
17. Patients' wishes regarding treatment are respected by oncologists.	☐	☐	☐	☐	☐
18. Patients understand their plan of care/treatment.	☐	☐	☐	☐	☐
19. Patients understand their prognoses and therapy goals.	☐	☐	☐	☐	☐
20. Patients' prognoses are usually well explained.	☐	☐	☐	☐	☐
21. Patients want to be informed.	☐	☐	☐	☐	☐
22. When being told about their therapy, most patients pay more attention to potential benefits of therapy than side effects.	☐	☐	☐	☐	☐
23. Most Patients are willing to accept side effects for even a small benefit of therapy.	☐	☐	☐	☐	☐
24. Patients are often frightened to ask questions.	☐	☐	☐	☐	☐
25. Patients' decisions whether to accept or not accept toxic chemotherapy is strongly influenced by their family preferences.	☐	☐	☐	☐	☐
26. Oncologists believe that patients are willing to accept side effects for even a small benefit of therapy.	☐	☐	☐	☐	☐

Appendix B

DUQUESNE UNIVERSITY

600 FORBES AVENUE ♦ PITTSBURGH, PA 15282

School of Nursing
Graduate Programs
5th Floor Fisher Hall
Telephone: 412.396.6550

DUQUESNE UNIVERSITY
INSTITUTIONAL REVIEW BOARD
APPROVAL DATE: 5-24-06
EXPIRATION DATE: 5-24-07

Dear Oncology Nurse:

I am requesting your participation in my dissertation research study that looks at an understudied area of cancer nursing practice –nurses' attitudes towards cancer clinical trials and their perceptions of patients' understanding of the treatments as well as a desire for information. The benefit to oncology nurses is to help in the understanding of this aspect of practice. Your completion of the forms in this packet would help to describe this important area of practice. Your participation in this study is voluntary.

You were randomly selected to participate in this survey from ONS members who indicated that their primary functional area was patient care or research with adult patients and any primary position other than researcher/principal investigator. If you do not meet these criteria please place a check mark in this box ☐ and mail this letter back to me in the enclosed stamped addressed envelope. If you do meet these criteria please complete the study forms as outlined below.

There is no right or wrong answer regarding your attitudes and perceptions about cancer clinical trials. There are no foreseeable risks to you. Your answers will be kept confidential and pooled with those of other respondents to describe this element of practice. The only identification will be a numeric code on the return envelope which corresponds with a code on a master list of potential participants. When you return the completed survey, your name will be deleted from the mailing list and never connected to your answers in any way. At the end of the study all the codes and remaining address labels will be destroyed by the researcher. There are two forms for you to complete in this packet that should take fewer than ten minutes to complete:

- The Nurses' Attitudes Survey (modified) contains statements regarding your attitude toward the benefits of clinical trials, your perceptions of patient understanding, and your perceptions about patients' reasons for participating as research subjects.
- Demographic Information Form which asks for information such as age, education level, functional role, practice setting etc.

When you are finished, place all the materials in the stamped, addressed envelope provided and mail it to me. Your response will be your implied consent. If you have any questions, please at 631-987-4695 or my dissertation chair Dr. Gladys Husted at 412-396-6544. If you have any further questions about your rights regarding this study you may call Dr. Paul Richer, Chair of the Duquesne University Institutional Review Board (IRB) at 412-396-6326.

In advance, thank you for helping to describe this aspect of cancer nursing practice.

Sincerely,

Paul G. D'Amico

Paul G. D'Amico, MS, RN, OCN, PhD(c)
Doctoral Student Duquesne University School of Nursing

Appendix C

Demographic Information Form

The following information is requested so that the investigator may gain a better understanding of demographic characteristics related to the nurse-patient. **Please answer all questions by checking the appropriate box or filling in the blank**

1. What is your age? _____ years old (*please insert a number*)

2. Your gender: ☐ Female ☐ Male

3. Indicate your highest level of nursing education.

Check Level	**Educational Level**
☐	Diploma in nursing
☐	Associate degree in nursing
☐	Associate degree in another field
☐	Baccalaureate degree in nursing
☐	Baccalaureate degree another field
☐	Master's degree in nursing
☐	Master's degree in another field
☐	Doctoral degree in nursing
☐	Doctoral degree in another field

4. Do you work with or care for patients contemplating enrollment in or currently enrolled in cancer clinical trials?

☐ Yes ☐ No

5. What certifications do you have in oncology nursing? (Check all that apply, if none go to question #6).

<u>Certification Type</u>

Oncology Certified Nurse (OCN) ☐ Yes

Advanced Oncology Certified Nurse (AOCN) ☐ Yes

Advanced Oncology Nurse Practitioner (AOCNP) ☐ Yes

Advanced Oncology Clinical Nurse Specialist (AOCNS) ☐ Yes

☐ Other_____(*please specify)*

6. Number of years an RN
Please indicate your total number of years of experience as a RN where you had direct patient contact at least 8 hours per week. (Round to the nearest whole year)._____years (*please insert a number*).

7. Number of years an RN in Cancer Care
Please indicate your total number of years of experience as a RN in CANCER care where you had direct patient contact at least 8 hours per week.
(Round to the nearest whole year)._____years (*please insert a number*)

8. Percentage of patients offered cancer clinical trials
At your place of employment/practice setting, what percentage of patients are offered any type of cancer clinical trials? (eg. NCI sponsored, industry sponsored, investigator initiated studies)._____ % (*please insert a number*)

9. What is your primary work setting? (*Select one*)

In-patient
- ☐ Bone Marrow Transplant Unit
- ☐ Intensive Care Unit
- ☐ Medical/Surgical Unit- General
- ☐ Medical/Surgical Unit-Oncology
- ☐ Oncology Specialty Unit
- ☐ Other_____ (please specify)

Outpatient
- ☐ Home Care
- ☐ Hospice
- ☐ Hospital Based Clinic/Infusion Center
- ☐ Physician Office
- ☐ Radiation-Free Standing
- ☐ Radiation-Hospital Based
- ☐ Other_____ (please specify)

Other
- ☐ Corporate/Industry
- ☐ Extended Care Facility
- ☐ HMO/Managed Care
- ☐ School of Nursing
- ☐ Self Employed
- ☐ Other_____ (please specify)

10. What is your primary position? (*Select one*)

☐ Staff Nurse	☐ Clinical Nurse Specialist	☐ Nurse Practitioner
☐ Nurse Educator	☐ Clinical Trials Nurse	☐ Nurse Researcher
☐ Nurse Manager	☐ Academic Educator	☐ Case Manager

- ☐ Other_____ (please specify)

Appendix D

Paul D'Amico

From: Meropol, M.D., Neal [NJ_Meropol@fccc.edu]
Sent: Monday, September 20, 2005 9:52 AM
To: 'Paul D'Amico'
Subject: RE: Dissertation

Paul,
Thank you for the follow up again, and good luck with your thesis. Feel free to modify the instrument as you propose. I'll be most interested in your results.
This e-mail should be sufficient for you to proceed comfortably.

Neal J. Meropol, M.D.
Fox Chase Cancer Center
333 Cottman Avenue
Philadelphia PA 19111
phone: (215)728-2450
fax: (215)728-3639

-----Original Message-----
From: Paul D'Amico [mailto:damicop@duq.edu]
Sent: Monday, September 20, 2005 9:31 AM
To: nj_meropol@fccc.edu
Subject: Dissertation

Dear Dr. Meropol,

I hope you are well. Once again I want to bring you up to date with my doctoral
dissertation.

As I previously informed you, I want to use your Nurses' Attitude Survey in my data collection and want to modify it by removing the section on "Nurses' Role in a Comprehensive Cancer Center" since this is beyond the scope of my study.

Additionally, I want to remove the areas for written comments (have the subjects only answer the Likert scale items) and I want to capture the demographic information on a separate form and remove it from the Nurses' Attitude Survey.

If you think we can modify the tool as outlined above, then I will need a signed letter from you, giving me permission to use your tool in a modified form for my dissertation.

Thank you for reading this e-mail,

Sincerely,

Paul D'Amico

Appendix E

DUQUESNE UNIVERSITY

School of Nursing
Graduate Programs
5th Floor Fisher Hall
Telephone: 412.396.6550

600 FORBES AVENUE ♦ PITTSBURGH, PA 15282

Dear Oncology Nurse,

Three weeks ago a survey packet was mailed to you. I am conducting research for my doctoral dissertation and I am seeking your attitudes toward cancer clinical trials and your perceptions of patient understanding. Your participation in this study is voluntary.

You were randomly selected to participate in this survey from ONS members who indicated that their primary functional area was patient care or research with adult patients and any primary position other than researcher/principal investigator. If you do not meet these criteria please place a check mark in this box ☐ and mail this letter back to me in the enclosed stamped addressed envelope. If you do meet these criteria please complete the study forms as outlined below

If you have completed and returned your survey to me, please accept my sincere thanks. If not, please do so today. I am grateful for your help because your attitudes and perceptions regarding clinical trials are important to oncology nursing and to help us understand this aspect of cancer care.

If you have misplaced the survey another one is included with a stamped, addressed return envelope.

There are two forms for you to complete.

- The Nurses' Attitudes Survey (modified) contains statements regarding your attitude towards benefit of clinical trials, your perceptions of patient understanding, and your perceptions about patients' reasons for participating as research subjects.
- Demographic Information Form which asks for information such as age, education level, functional role, practice setting etc.

It should take you less than 10 minutes to complete the forms.

When you are finished, place all the materials in the stamped, addressed envelope provided and mail it to me. Your response will be your implied consent. If you have any questions, please at 631-987-4695 or my dissertation chair Dr. Gladys Husted at 412-396-6544. If you have any further questions about your rights regarding this study you may call Dr. Paul Richer, Chair of the Duquesne University Institutional Review Board (IRB) at 412-396-6326.
.
In advance, thank you for helping to describe this aspect of cancer nursing practice.

Sincerely,

Paul G. D'Amico, RN, MS, OCN, PhD(c)
Doctoral Student Duquesne University School of Nursing

Appendix F

DUQUESNE UNIVERSITY
INSTITUTIONAL REVIEW BOARD
424 RANGOS BUILDING ♦ PITTSBURGH, PA 15282-0202

Dr. Paul Richer
Chair, Institutional Review Board
Phone (412) 396-6326 Fax (412) 396-5176
e-mail: richer@duq.edu

May 24, 2006

Mr. Paul D'Amico
702 Hilltop Court
Coram NY 11727

Re: "Oncology nurses' attitudes toward cancer clinical trials and their perceptions of patient understanding" (Protocol # 06-68)

Dear Mr. D'Amico:

Thank you for submitting your research proposal and the requested revisions.

Based upon the recommendation of IRB member, Dr. Joan Masters, along with my own review, I have determined that your research proposal is consistent with the requirements of the appropriate sections of the 45-Code of Federal Regulations-46, known as the federal Common Rule. The intended research poses no greater than minimal risk to human subjects. Consequently, under rules 46.101 and 46.110, your proposed research is approved on an **expedited** basis.

The letter that serves as informed consent will be stamped with IRB approval on the letterhead page. You should use the stamped forma as the originals for copies that potential subjects read.

This approval must be renewed in one year as part of the IRB's continuing review. You will need to submit a progress report to the IRB in response to a questionnaire that we will send. In addition, if you are still utilizing your informed consent letter, you will need to have it approved and stamped for another year's use.

In any correspondence about this study, please refer to the ID number following the title above.

If, prior to the annual review, you propose any changes in your procedure or consent process, you must inform the IRB Chair of those changes and wait for approval before implementing them. In addition, if any procedural complications or adverse effects on subjects are discovered before the annual review, they immediately must be reported to the IRB Chair before proceeding with the study.

When the study is complete, please provide us with a summary, approximately one page. Often the completed study's Abstract suffices. Please keep a copy of your research records, other than those you have agreed to destroy for confidentiality, over a period of five years after the study's completion.

Thank you for contributing to Duquesne's research endeavors.

If you have any questions, feel free to contact me at any time.

Sincerely yours,

Paul Richer/mv

Paul Richer, Ph.D.
IRB Chair

C: Dr. Joan Masters
Dr. Gladys Husted
IRB Records