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**An Exploratory Study of Pediatric Oncology Nurses' Perceptions of and  
Advocacy Responses to Ethical Issues in Securing Informed Consent in  
Adolescent and Young Adult Patients**

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Advocacy Responses to Ethical Issues in Securing Informed Consent in  
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**by**

**Virginia Diane Chandlee, MSN, BSN, RN**

**Dissertation**

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## **Dedication**

This work is dedicated to my loving husband, Kevin, who is my forever and always.

To my parents: Juanita & Theodore Oppermann, who taught me that education is lifelong  
and always knew I could.

To my three children: Sara, Emma, and Kevin, who shared me with UTMB during this  
more than six year journey.

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# **An Exploratory Study of Pediatric Oncology Nurses' Perceptions of and Advocacy Responses to Ethical Issues in Securing Informed Consent in Adolescent and Young Adult Patients**

Publication No. \_\_\_\_\_

Virginia Diane Chandlee, PhD, RN

The University of Texas Medical Branch, 2020

Supervisor: Dr. Darlene Cheyenne Martin

The purpose of the proposed study was to explore pediatric oncology nurses' perceptions of ethical issues that may arise in the process of obtaining informed consent in adolescent and young adult patients (aged 16-24 years) who participate in clinical research trials and to examine if nurses engage in advocacy on behalf of these patients.

A descriptive, exploratory research design utilizing an anonymous online survey was used for this study. The sample consisted of registered nurses living in the United States currently employed full or part-time in direct care roles with pediatric oncology patients.

A total of 270 participants was recruited from three sources: 1) a contact population of pediatric oncology nurses via email using purposive sampling design techniques through an online database service specializing in health care marketing and research, 2) a contact population of pediatric oncology nurses via email using purposive sampling design techniques through the pediatric specialty organization member list, and 3) by email invitations submitted to former colleagues and pediatric nurse educators at national cancer hospitals with pediatric oncology units.

Data was analyzed using descriptive statistics (variance, and standard deviation), tests of differences, analyses of covariance, and correlation (Pearson's and Partial Correlations). A statistical significance of  $\alpha < .05$  was the standard used for this research.

Results of the research study provided new data and insights about pediatric oncology nurses' perceptions of ethical issues that often arise in obtaining informed consent in adolescent and young adult cancer patients and nurses' advocacy behavioral actions on behalf of this population. Published results will help fill a gap in current oncology research literature.

## TABLE OF CONTENTS

<b>LIST OF TABLES.....</b>	<b>ix</b>
<b>LIST OF FIGURES .....</b>	<b>xi</b>
<b>LIST OF ABBREVIATIONS.....</b>	<b>xii</b>
<b>CHAPTER 1: INTRODUCTION .....</b>	<b>1</b>
Introduction.....	1
Problem Statement .....	1
Background .....	3
Significance.....	6
Theoretical Framework .....	8
Conceptual Definitions .....	11
Description of Variables .....	12
Purpose and Goal .....	12
Specific Aims and Research Questions .....	13
Summary .....	15
<b>CHAPTER 2: REVIEW OF LITERATURE.....</b>	<b>16</b>
Introduction.....	16
Informed Consent Studies.....	24
Nursing Advocacy Studies .....	32
Summary of Literature .....	35
<b>CHAPTER 3: RESEARCH DESIGN AND METHODOLOGY.....</b>	<b>37</b>
Introduction.....	37
Research Design.....	37
Sample, Setting and Recruitment.....	38
Inclusion Criteria .....	38
Exclusion Criteria .....	39
Data Collection .....	39

Data Management .....	40
Instrumentation .....	41
Demographic Data Information Sheet .....	41
Nursing Ethics Questionnaire (NEQ) .....	42
Protective Nursing Advocacy Scale (PNAS).....	44
Protection of Human Subjects .....	45
Limitations and Assumptions.....	46
Data Analysis .....	47
<b>CHAPTER 4: RESULTS.....</b>	<b>51</b>
Introduction.....	51
Pediatric Nurse Oncology Demographic Characteristics .....	52
Internal Consistency and Validity for Instruments .....	55
Preliminary Analysis.....	56
Study Questions .....	63
Other Findings of the Study: Narrative Question.....	91
Chapter Summary .....	97
<b>CHAPTER 5: DISCUSSION AND RECOMMENDATIONS.....</b>	<b>99</b>
Introduction.....	99
Demographic Characteristics .....	100
Discussion of Major Findings.....	102
Summary of Findings.....	109
Theoretical Framework Relationship.....	110
Strengths .....	111
Study Limitations.....	112
Implications for Nursing .....	112
Recommendations for Future Research .....	114
Conclusions.....	115
<b>APPENDIX A: DEMOGRAPHIC DATA INFORMATION SHEET.....</b>	<b>116</b>
<b>APPENDIX B: NURSING ETHICS QUESTIONNAIRE (NEQ).....</b>	<b>117</b>
<b>APPENDIX C: PROTECTIVE NURSING ADVOCACY SCALE (PNAS).....</b>	<b>119</b>



<b>APPENDIX D: RECRUITMENT EMAIL.....</b>	<b>120</b>
<b>APPENDIX E: IRB APPROVAL LETTER.....</b>	<b>122</b>
<b>APPENDIX F: PRELIMINARY FACTOR ANALYSIS RESULTS - NEQ.....</b>	<b>124</b>
<b>APPENDIX G: PRELIMINARY FACTOR ANALYSIS RESULTS - PNAS .....</b>	<b>126</b>
<b>REFERENCES.....</b>	<b>128</b>
<b>VITA.....</b>	<b>143</b>

## LIST OF TABLES

Table 4.1: Demographic Characteristics of Pediatric Oncology Nurse Sample.....	53
Table 4.2: Pearson's Correlation of Demographic Data.....	54
Table 4.3: Cronbach's alpha for Instruments and Subscales .....	56
Table 4.4: KMO and Bartlett's Test for Instruments.....	57
Table 4.5: NEQ Forced Factor Analysis with Varimax Rotation.....	58
Table 4.6: PNAS Forced Factor Analysis with Varimax Rotation.....	60
Table 4.7: Cronbach's alpha for Revised NEQ and Subscales.....	62
Table 4.8: Revised NEQ Subscales post Factor Analysis.....	62
Table 4.9: Summary Descriptive Statistics of NEQ subscales.....	64
Table 4.10: Nurses' Perceptions of AYA's Decision-Making Skills - NEQ-1.....	65
Table 4.11: Nurses' Perception of the Informed Consent Process - NEQ-4.....	66
Table 4.12: Nurses' Perception of AYAs' Knowledge of Clinical Trials - NEQ-5...	67
Table 4.13: Summary Statistics of NEQ & Subscales by Years of Experience.....	69
Table 4.14: Pearson's Correlations for NEQ Scale.....	70
Table 4.15: Independent T Test for NEQ by Years of Nursing Experience.....	72
Table 4.16: Mann-Whitney U Results for the NEQ.....	73
Table 4.17: Summary of NEQ Item Responses that Differed.....	74
Table 4.18: Levene's Test for Equality of Variances & Independent T test.....	75
Table 4.19: Mann Whitney U test Results for the 5 NEQ items.....	76
Table 4.20: Summary Descriptive Statistics of PNAS and Subscales.....	78
Table 4.21: Acting as an Advocate – PNAS-1.....	79

Table 4.22: Work Status and Advocacy Actions – PNAS-2 .....	80
Table 4.23: Summary Statistics of PNAS & Subscales by Years of Experience .....	81
Table 4.24: Pearson’s Correlations for the PNAS Scale.....	83
Table 4.25: Independent T Test for PNAS & Subscales by Years of Nursing.....	83
Table 4.26: Pearson’s Correlations for the NEQ and PNAS Scales.....	86
Table 4.27: NEQ vs. PNAS for Years of Oncology Nursing Experience.....	88
Table 4.28: Partial Correlations of NEQ and PNAS.....	90
Table 4.29: Narrative Question Responses for Informed Consent.....	93
Table 4.30: Narrative Question Responses for Nurse Advocacy.....	96

## LIST OF FIGURES

Figure 4.1: Scree Plot for NEQ after Forced Factor Analysis .....	59
Figure 4.2: Scree Plot for PNAS after Forced Factor Analysis .....	61
Figure 4.3: Scatter Plot of Years of Nursing Experience vs NEQ Total Score .....	71
Figure 4.4: Scatter Plot of PNAS Scale vs. Years of Nursing Experience .....	84
Figure 4.5: Scatter Plot of NEQ total score to PNAS total score .....	87

## **LIST OF ABBREVIATIONS**

AAP	American Academy of Pediatrics
ANA	American Nurses Association
ANOVA	Analysis of Variance
AYA	Adolescent and Young Adult
CDC	Center for Disease Control
CNS	Central Nervous System
DHHS	Department of Health and Human Services
EOL	End of Life
FA	Factor Analysis
GSBS	Graduate School of Biomedical Science
ICN	International Council of Nurses
IOM	Institute of Medicine
KMO	Kaiser-Meyer-Olkin measure of sampling adequacy
NCI	National Cancer Institute
NEQ	Nurses' Ethics Questionnaire
OCN	Oncology Certified Nurse
PCA	Principle Components Analysis
PNAS	Protective Nursing Advocacy Scale
UTMB	University of Texas Medical Branch

## **CHAPTER 1: INTRODUCTION**

### **INTRODUCTION**

This dissertation is organized into five chapters, including appendices, tables, figures, and a reference list. Chapter One introduces the dissertation research study by fully describing the problem, purpose, and significance of the study. Furthermore, it outlines the theoretical framework, defines the variables, the specific aims and research questions, and gives a brief overview of the study design. Chapter Two presents a review of the related literature regarding informed consent in the pediatric, adolescent, and young adult population to date. Relevant nursing advocacy studies are also presented. Chapter Three describes the research design and methodology of the study, including data collection procedures, sampling, and data analysis. Chapter Four provides the study results and findings. Chapter Five includes an in-depth discussion section and synthesis of the research findings and current literature, as well as conclusions and recommendations for future nursing research.

### **PROBLEM STATEMENT**

Currently, there are more than 13,000 new cases of cancer per year diagnosed in adolescent and young adults (ages 15 to 24 years) and more than 47,000 survivors aged 15 to 19 years that are living in the United States (Miller, et. al, 2016). This age group comprises nearly 2% of all invasive cancers and is more than 2.7 times more likely to be diagnosed with cancer than those in the first fifteen years of life (Bleyer, et. al, 2006).

Overall cancer incidence in children and adolescents has been increasing slightly (by 0.6% per year), with the increased number of leukemias diagnosed contributing to the overall rise, along with lymphomas and brain tumors (Siegel, et al., 2018). Based on data from SEER 18 Cancer Statistics Review, an estimated 84.6% of children and adolescents diagnosed with leukemia and 74.9% with central nervous system (CNS) tumors survive at least 5 years after treatment (Noone et al., 2017). However, in spite of increasing survival rates, many adolescents do not respond as well overall to the experimental or conventional treatments as either younger or older patients with similar cancer types. Adolescents often have to undergo additional treatments beyond the five year period due to relapse, new variants of the original cancer, or related illnesses. Researchers suggest the biological course of these specific cancers in this adolescent age group may differ substantially from the disease trajectory in other populations (Keegan, et al., 2016).

The increase in cancer rates and overall survival among the adolescent and young adult (AYA) population has a direct impact on pediatric oncology nurses' clinical practice across the United States. Nurses are in a unique position to work closely with adolescent and young adult oncology patients who must navigate the difficult and often confusing and detailed process of giving informed consent to receive cancer-directed treatment protocols and treatments. While informed consent is an issue for all age groups, it particularly affects the adolescent and young adult since there is limited research regarding the quality and comprehension for this particularly vulnerable group. Most literature related to informed consent addresses issues related to children with cancer and parental decision-making or examines comprehension and understanding of consent among adults. Pediatric oncology nurses interact with the researchers, the patients, and

families in discussions of informed consent and may answer questions for the adolescent and young adult on all aspects of treatment for a life-threatening illness (Newman, et al., 2019). In addition, recent research also points to a rise in diagnoses of specific forms of cancer including leukemias, lymphomas, and brain tumors among the adolescent population (Siegel et al., 2018) and a decreased enrollment of this age group in experimental cancer clinical trials in the United States (Aristizabal, et al., 2015; Collins, et al., 2015; Parsons, et al., 2011; Shaw & Ritchey, 2007).

In spite of the increase in cancer rates and in enrollment in cancer clinical trials among the adolescent and young adult (AYA) population, there has been limited research and scholarship examining the unique ethical and legal issues which may arise during the consent process with this specific age group of patients. There is also limited research exploring the oncology nurse's experiences and views about consent dilemmas and possible advocacy roles they may engage in to help assure adequacy, truthfulness, and understanding of the informed consent process. However, oncology nurse clinicians are increasingly recognized as integral members of experimental cancer research teams. These nurses play a vital role in helping adolescent and young adult oncology patients navigate, often for the first time, the difficult, detailed, and frequently confusing process of giving informed consent to receive cancer-directed treatment protocols and procedures (Rebers, et al., 2016; Padberg & Flach, 1999).

## **BACKGROUND**

Increasing recognition over the past several decades from bioethicists, legal scholars, federal regulatory agencies, and health professionals exists that older children



and adolescents should have some level of involvement in the informed consent process regarding their overall medical treatment and participation in clinical trials (Katz & Webb, 2016; Holder, 2010; Annas, 2004; Institute of Medicine, 2004). Much of the related dialogue and debate focuses on the legal rights and scope of parents to make treatment decisions on behalf of their children, as well as, the extent to which older children and adolescents have ethical and legal rights, and sufficient capacity to understand proposed treatments and to have a voice in assenting or consenting to treatment decisions which directly affect them (Cherry, 2017; AAP, 2016; Coleman & Rosoff, 2013; Steinberg, 2013; Joffe, et al., 2006).

The American Academy of Pediatrics Committee on Bioethics, citing the evolving maturation and decision capacity of older children and adolescents over time, has been at the forefront of efforts since the 1970's to promote the concept of assent and consent in pediatrics citing the evolving maturation and decision capacity of older children and adolescents. The Committee further noted that seeking assent or consent from this age group may help foster moral growth and development of autonomy (Katz & Webb, 2016; AAP, 2016; Joffe, et al., 2006)). An important distinction is, although securing assent and informed consent from children and adolescents is recommended for overall clinical care, that it is mandated by federal regulations that older children and adolescents considered for experimental cancer clinical trials be consulted and when possible give informed assent or consent (IOM, 2004). Guidelines for inclusion are codified in IRB regulations (1977), as well as, in NIH policy and guidelines (2015) on children as research subjects and other federal guidelines, including 45 CFR part 46 or the "common rule" (Menikoff, et al., 2017). In these guidelines, parents are clearly seen

as having primary decision-making authority for younger children and adolescents to be enrolled in clinical trials research, but researchers are required to involve older adolescents and young adults in the consent process and to secure their informed consent.

There are several categories of adolescent minors, typically under the age of 18, who may be able to make medical decisions about participation in research without parental consent based on specific state laws. These include minors who can be considered as emancipated from their parents before reaching the age of majority through marriage, military service, or living separately from their parents and self-supporting. Although not consistent by federal mandate, some states provide that certain minors can be considered as medically emancipated if they have had a long-term chronic illness and are very knowledgeable about their treatment and related risks. Most states have also adopted the “Mature Minor Doctrine” that allows minors to consent to medical care considered routine, non-emergency care with a low risk of harm, although this typically excludes experimental cancer clinical trials (Steinberg, 2013; IOM, 2004).

The concept of nursing advocacy, nurses acting on the behalf of their patients, is embedded in the American Nurses Association (ANA) Code of Ethics - Provision 3 states that nurses “promote, advocate for, and protect the rights, health, and safety of the patient” (ANA, 2015, p. v). The International Council of Nurses (ICN) position statement further explains that the scope of nursing practice is a “combination of knowledge, judgement and skill that allows the nurse to perform direct care giving and evaluate its impact, advocate for patients and for health, supervise and delegate to others, lead, manage, teach, undertake research and develop health policy for health care systems” (ICN, 2013, p. 1). In addition, the American Nurses Association (ANA)

recently defined advocacy as “the act or process of pleading for, supporting, or recommending a cause or course of action”, either for persons or for an issue (ANA, 2015, p. 57). Both the ANA and the ICN clearly promote advocacy as a call to action on the part of nurses to ensure every patient receives quality health care treatment in a safe environment. Gerber (2018), Selander, et al., (2012), and Grace (2001) also reported that advocacy is acknowledged as a part of ethical nursing practice, and an important philosophical principle helping to assure patient rights and safety. The nurse is an advocate, both when working to achieve quality patient outcomes and when patients are unable or unwilling to advocate for themselves.

## **SIGNIFICANCE**

While informed consent can be problematic for patients of all ages, it may be particularly challenging for older adolescents and young adults, who are between adolescence and adulthood, as they are asked to assume a role as the primary decision-maker for their experimental cancer treatment instead of their parents or guardians. Pediatric oncology nurses are often the link between researchers, patients, and families participating in important informed consent discussions, regarding patients’ concerns and questions about treatment of their life-threatening illnesses (Joffe, et al., 2006; Ruccione, 1994). There is ample research addressing the informed consent process in adult patients regarding treatments and procedures and the assent process in the minor child. However, there is little research about the informed consent process and comprehension in adolescents and young adults, 16-24 years of age. In addition, pediatric oncology nurses have not been previously studied in the literature to ascertain if they view themselves as

advocates in the implementation of informed consent for this age group, as well as, their assessment of the adequacy of the informed consent process itself. The purpose of the study is to investigate pediatric oncology nurses' advocacy behaviors as well as, the nurses' perceived knowledge of the adequacy and comprehension of informed consent of adolescent and young adults, 16-24 years of age. This age-group of pediatric patients comprise a portion of the population who consents to clinical trials, while developmentally they may not yet be mature enough to fully comprehend the outcomes of their decisions. Furthermore, the outcomes of this research seeks to explore if experienced nurses see themselves as advocates and if they evaluate the adequacy of the informed consent process in a different manner than the inexperienced or new nurse with less than five years' experience. The major gaps addressed by this study include the presence or absence of nursing protective advocacy behaviors in the inexperienced versus the experienced nurse, the adequacy or inadequacy of the informed consent process, and the relationships of these variables with various demographic characteristics.

This research may enhance knowledge of protective advocacy behaviors in both experienced and inexperienced pediatric oncology nurses as well as their perceptions of the quality of informed consent in adolescent and young adult patients. The importance of this research is underscored by the need to support both experienced and inexperienced nurses working with a vulnerable population of still developing adolescents. Current and subsequent studies could provide substantive data that have the potential to positively change nursing practice by modifying nurses' approach to adolescent and young adult patients confronting treatment decisions. The research objectives associated with the specific aims of this study are significant because they examine nurses' perceptions about

the quality of the informed consent process in adolescent and young adult oncology patients as well as the extent to which nurse engage in protective advocacy to protect the health and well-being of these patients. Exploring the quality of informed consent in adolescent and young adult populations can contribute to a knowledge base that helps further discussion and research that can be used to address consent issues that may arise in other treatments for this age group such as reproductive health, mental health, chronic disease progression, and risk factors for future disease processes.

## **THEORETICAL FRAMEWORK**

The unique framework that was used to guide this research study was Gadow's (1980) theory of existential advocacy. The adolescent and young adult cancer patient can be among the most vulnerable of all who seek treatments for their life-threatening illnesses. The cancer diagnosis and long and arduous treatment plan can render adolescents and young adults powerless and unaware of the best course of action to pursue without clinical guidance. In addition, all courses of treatment may be marked by the uncertainty of the outcomes of disease progression, remission, and long term sequelae. As a result, adolescent and young adult patients may experience a feeling of loss of personal control and an increased reliance on others to help guide and educate them regarding the best course of action. The nurse advocate is in the unique position to support adolescent and young adult patients, along with their families, as they may require assistance in understanding the meaning of their long term illness and treatment, and how it will affect their health, future plans, and overall well-being (Bishop & Scudder, 2003). Pediatric oncology nurses, as advocates, can assist adolescent and young

adult patients to discern and clarify their personal beliefs, values, and goals that Gadow (1989) sought to integrate with the available treatment options for their illness.

Informed consent is not just relaying all of the facts regarding the disease process and progression, treatments, and statistics for survival. Adolescents and young adults must also weigh all of the disclosed information and choose the course of action that best meets the values, beliefs, and goals that they have set for their future, while also considering their decisions within the milieu of their family (Sibley, et al. 2018; Cherry, 2017; Madden, et al., 2016; Baines, 2011). Whether or not an adolescent young adult has the capacity to provide informed consent is a realistic question; it is presumed that adults have the capacity to provide informed consent, but the opposite is true for children (Santelli et al., 2017). While the adolescent and young adult with a cancer (because of their long term experience with the diagnosis) may have the capacity to provide a true informed consent, more research is needed in this area to understand and support their capacity to make informed decisions.

Since this research study focused on pediatric oncology nurses establishing a relationship of trust while promoting both patient autonomy and self-determination, Gadow's (1980) framework of existential advocacy provides a meaningful framework nurse and patient's interactions. Gadow proposed that one of the central roles is "the nurse's participation with the patient in determining the unique meaning which the experience of health, illness, suffering, or dying is to have for that individual" (p. 81). Accordingly, her premise is "based upon the principle that freedom of self-determination is the most valuable human right" (p. 84). Gadow stressed that the ideal nurse-patient

relationship affirms that patients have the right to decide for themselves about all personal matters, which include health care decisions.

Gadow (1989a) further affirmed that the informed consent process is one that includes both subjective and objective information identified by the nurse, as an advocate, who assists the adolescent and young adult to understand the often complex medical diagnosis and proposed treatment regimen presented during the informed consent process. She also asserts (1989a) that the nurse, in the role of advocate, helps the adolescent/young adult assess the personal meaning and potential impact of this diagnosis and treatment on their current life and goals for the future. She concluded that the actions of the nurse advocate support the autonomy of the patient (Gadow, 1989b).

In the model, it is the patient who must determine their beliefs and goals of health; the nurse assists the patient in defining and establishing their beliefs. Gadow reiterates that the nurse advocate enables the adolescents and young adults to decide what to do for themselves. Through self-examination, patients can find meaning in their own experience (Gadow, 1989b). In addition, nurses participate in the informed consent process by assessing the adolescent and young adult's comprehension of the current course of treatment and by continuing to aid them in clarifying relevant information as it relates to their goals and beliefs for their health and future. Gadow (1989a) also integrates other aspects of life-threatening illness into the nurse's advocacy role: fear of the unknown, desire to be cured, reluctance to address end-of life decisions, and the health care professional's own investment in treatment for the young individual. It is these issues that increase the adolescent and young adult's vulnerability and affects their ability to make a decision without the advocacy of the professional nurse.

By incorporating Gadow's (1980) Theory of Existential Advocacy as the theoretical framework of the research study, factors contributing to adolescent and young adult's self-determination and autonomy can be explored. Pediatric oncology nurses' perceptions and advocacy action behaviors during the informed consent process can also be explored.

## CONCEPTUAL DEFINITIONS

*Advocacy* for this study is defined as "work on behalf of self and/or others to raise awareness of a concern and to promote solutions to the issue" (Tomajan, 2012). Nursing advocacy has its origin in the legal definition of advocate, defined as "a person who assists, defends, pleads, or prosecutes for another" (Garner, 2000, p. 43). American Nurses Association (ANA) recently defined advocacy as "the act or process of pleading for, supporting, or recommending a cause or course of action", either for persons or for an issue (ANA, 2015, p. 57). Hanks (2008a, 2008b) indicated nursing advocacy as "communicating with and informing patients, protecting patients, speaking out and speaking for patients, and building relationships."

*Informed Consent* is defined as the "knowing consent of an individual or legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion" (DHHS, 1981). Informed consent entails "providing information, assessing comprehension of the information provided, and ensuring the consent is voluntary and not coerced by circumstances" (Santelli, et al., 2017, p. 2).

*Assent* is a child's (or adolescent under the age of majority) affirmative agreement to participate in research (Field, & Behrman, 2004; Santelli, et al., 2017). The concept of assent recognizes the emerging developmental capacity of children, even where they may not be fully



capable of providing informed consent. It includes the following: achievement of a developmentally appropriate awareness of the condition, information related to tests and treatment, a professional clinical assessment of the minor's understanding of the situation, and an expression of willingness of the child to accept the proposed care (AAP, 2016; Katz & Webb, 2016)

*Adolescent and Young Adult (AYA)* is defined for this research study as any person or persons between the ages of 16 and 24 years of age.

## **DESCRIPTION OF VARIABLES**

- *Years of Nursing Experience* - measured by direct inquiry on the demographic survey as a count of years since RN licensure.
- *Advocacy Behaviors* - measured by the PNAS-1: Acting as Advocate -16 items and PNAS-2: Work Status and Advocacy Action - 5 items
- *Adequacy of the Informed Consent Process* - measured by NEQ-1: Decision-Making – 9 items, NEQ-4: Informed Consent – 13 items, and NEQ-5: Patient Knowledge – 6 items

## **PURPOSE AND GOAL**

The purpose of the study was to explore pediatric oncology nurses' perceptions of ethical issues that may arise in the process of obtaining informed consent in 16-24 year old adolescent and young adult oncology patients enrolled in experimental cancer clinical trials and to examine the extent to which the nurses engaged in protective advocacy behaviors related to informed consent on behalf of these patients. In addition, the study examined whether years of nursing experience correlated with the nurses' perceptions about the ethical adequacy of the informed consent process and the extent to which they

engaged in protective advocacy behaviors on behalf of their adolescent and young adult patients. The goals of this study were 1). to explore pediatric oncology nurses' perceptions of ethical issues related to the process of obtaining informed consent in the adolescent and young adult oncology patient, 2). to explore pediatric oncology nurses' perceptions of their advocacy behaviors regarding adolescent and young adult oncology patients who were enrolled in experimental cancer clinical trials, and 3). to examine if pediatric oncology nurses' protective nursing advocacy skills and behaviors were related to their perceptions of ethical issues that could arise in the process of obtaining adequate and fully understood informed consent in the care of adolescent and young adult oncology patients. Moreover, for all three goals, was there a relationship between the years of nursing experience and the pediatric oncology nurses' perception of the adequacy and understanding of the informed consent process and their advocacy behaviors when caring for the adolescent and young adult.

### **SPECIFIC AIMS AND RESEARCH QUESTIONS**

**AIM 1:** To explore pediatric oncology nurses' perceptions of ethical issues related to the process of obtaining informed consent in 16-24 year old adolescent and young adult oncology patients who were enrolled in experimental cancer clinical trials.

**RQ 1.1:** What are the perceptions of the informed consent process in adolescent and young adult patients as perceived by pediatric oncology nurses?

**RQ 1.2:** Is there a relationship between the years of nursing experience and nurses' perceptions about the adequacy and understanding of the informed

consent process in the 16-24 year old adolescent and young adult oncology patients?

**AIM 2:** To explore pediatric oncology nurses' perceptions about their advocacy behaviors regarding 16-24 year old adolescent and young adult oncology patients who were enrolled in experimental cancer clinical trials.

**RQ 2.1:** What are the perceptions of their nursing advocacy behaviors regarding adolescent and young adult patients by pediatric oncology nurses?

**RQ 2.2:** Is there a relationship between the years of nursing experience and the perceptions of pediatric oncology nurses about their advocacy behaviors for 16-24 year old adolescent and young adult oncology patients?

**AIM 3:** To examine if pediatric oncology nurses' protective nursing advocacy skills and behaviors are related to perceptions of ethical issues that may arise in the process of obtaining adequate and fully understood informed consent in the care of 16-24 year old adolescent and young adult oncology patients, and whether their years of nursing experience affect this relationship.

**RQ 3.1:** Is there a relationship between the pediatric oncology nurses' perception of advocacy behaviors (PNAS) and their perceptions about and experiences with ethical dilemmas they have encountered in obtaining informed consent (NEQ) from 16-24 year old adolescent and young adult oncology patients?

**RQ 3.2:** Do years of pediatric oncology nursing experience impact the relationship between nurses' perception of their advocacy behaviors (PNAS) and their perceptions about and experiences with ethical dilemmas they have

encountered in obtaining informed consent (NEQ) from 16-24 year old adolescent and young adult oncology patients?

## **SUMMARY**

This study explored pediatric oncology nurses' perceptions of and advocacy responses to ethical issues in securing informed consent in adolescent and young adult patients. In order to accomplish the study purpose and goals, a descriptive, exploratory research design was used for this study. In addition, nurse participants were given the opportunity to provide narrative responses to one optional, open-ended question regarding the pediatric oncology nurses' personal experiences with informed consent and/or advocacy in this age group. Their narratives were analyzed for categorical response frequencies.

Research findings may be meaningful and applicable to pediatric oncology nurses who work with adolescent and young adult cancer patients and families. The study examined nurses' perceptions about the process and quality of informed consent with this vulnerable population and identified advocacy behaviors that nurses engaged in to insure that the informed consent process was ethical and thorough prior to these young patients making decisions about entering clinical trials.

## **CHAPTER 2: REVIEW OF LITERATURE**

### **INTRODUCTION**

This chapter will present a review and critique of the extant literature that explored informed consent in the pediatric, adolescent, and young adult populations, and related research studies involving nursing advocacy behaviors are inherent in the interactions of nurses during the course of informed consent. Adolescent and young adult (AYA) patients have shown a decreased enrollment in cancer clinical trials when compared to their pediatric counterparts under fifteen years of age, especially for solid and CNS tumors (Aristizabal, et al., 2015; Collins, et al., 2015; Parsons, et al., 2011; Shaw & Ritchey, 2007). In 2006, the National Cancer Institute (NCI) identified the adolescent and young adult as a distinct health disparity population (Faulk, et al., 2020). Faulk et al. (2020) further revealed that research has identified additional factors leading to reduced enrollment for adolescent and young adult patients, such as: site of oncology treatment and care, low physician referral rates, sub-optimal health insurance coverage, poor clinical trial knowledge and questions regarding informed consent (Faulk, et al., 2020; Buchanan, et al., 2014; Parsons, et al., 2014; Parsons, et al., 2011; Ford, et al., 2008; Burke, et al., 2007). Unguru, et al. (2010) found that although the children wanted to be involved in the decision making, they exhibited a limited understanding of research even with their doctors' explanations and felt minimally involved in the decision to enroll in research clinical trials since their parents provided the consent. These findings highlight the need for pediatric oncology nurses to ensure both the quality and understanding of the informed consent process and recognize the nursing advocacy

behaviors and actions for the AYA patients so that quality of life outcomes and psychosocial factors remain at the forefront of care during the long course of treatment for this vulnerable and at risk population.

Informed consent for clinical research is regulated by the Department of Health and Human Services 45CFR part 46 (2018) that mandates the investigator obtain agreement to the basic elements of research after allowing the participant sufficient opportunity to discuss and consider whether or not to participate. It also requires that the information shared be only that which any reasonable person would want in language understandable to them without coercion or undue influence to make an informed decision as outlined by the Belmont Report of 1979 (DHHS, 2018; Adashi, et al., 2018; Bester, et al., 2016). When Appelbaum & Grisso (1988), in their seminal work, evaluated the rights of patients to accept or refuse treatment according to their decision making capacities, they concluded that patients had to be informed properly and given the chance to demonstrate mental functioning at their highest level of aptitude. Furthermore, they concluded that the legal standards for declaring competence included the skills of communicating a choice, understanding relevant information, recognizing the current situation and its consequences, and possessing the ability to weigh the possible choices. (Appelbaum & Grisso, 1988). Therefore, informed consent can be seen as an ongoing process that requires healthcare professionals to undertake it with expert knowledge, open communication, and a willingness to participate in shared decision-making with the patient, and the patient's guardian or parents if the patient is a minor (Bester, et al., 2016; Grady, et al., 2014; Varricchio & Jassak, 1989).

The American Academy of Pediatrics' policy statement for informed consent in

decision-making in pediatric practice committee on bioethics (2016) includes several standards that are applicable to this research with the understanding that pediatricians should be well-versed at talking to their patients on their developmental and cognitive level. First, that shared family-centered decision making is increasingly used and builds on collaborative communication between families and providers, and physicians should intervene if the patient is at risk for serious harm. Second, when mature adolescents have expressed wishes about their goals of care before deterioration of cognitive function, these wishes will be respected by parents and providers at the appropriate time. In addition, the parents' responsibility in informed consent is to support the interests of the child and to preserve the family relationship, instead of expressing their own individual choices. And lastly, when the mature adolescent minor faces a terminal illness with poor prognosis, it is important that pediatricians uphold the assent or refusal for continued treatment when facing end-of-life decisions (AAP, 2016; Katz & Webb, 2016; Caplan, 2007). Moreover, physicians should recognize that older adolescents with medical experience, because of chronic illness, can be minors with enough decision-making capacity, moral intelligence, and judgment to provide informed consent or informed refusal for their proposed care plan and should participate in the discussions (AAP, 2016; Katz & Webb, 2016).

Current research indicates that the adolescent brain is still evolving its emotional and intellectual maturation until approximately twenty-five years of age (Casey, et al., 2011; Cherry, 2017), and brain development could even progress well into the third decade of life (AAP, 2016; Katz & Webb, 2016). The decisions made by the adolescent and young adults' parents or guardians must encompass both health care needs and

treatments together with overall family dynamics, personal cultural beliefs, values, and goals (Katz & Webb, 2016; Cherry, 2015). Varricchio & Jassak (1989) emphasized that with the publication of the American Hospital Association's Patient Bill of Rights in 1973 (rev. 1992), the consent process moved from one of traditional physician disclosure to one of a shared decision-making between the physician and patient with the family. Physicians and providers can nurture the growth of autonomy and moral independence in young patients by including children and adolescents in the discussions of medical interventions and by seeking assent (Katz & Webb, 2016). An adequate assent process for the adolescent oncology patient under legal age should still be considered as essential as the informed consent process is for adults, even if parental permission is required by law.

Since pediatric research raises certain ethical and legal issues and children are presumed to have insufficient cognitive ability to consent to participate in research, it is difficult to know the appropriate age at which they can consent to cancer clinical trials (Knoppers, et al., 2016; Presidential Commission for the Study of Bioethical Issues, 2013; Levine, 2008). Counter-research demonstrates that adolescents, especially those age 14 and older, may have the same decisional skills necessary as adults 18 years of age and older. Indeed, in most states, 14 years is the age at which a minor is considered mature enough to consent to certain medical treatments, even if by state law that age can vary from age 12 to 15 years (Weisleder, 2004). Hence, there is a period of time when brain development is not complete and yet the adolescent and young adult after age 18 are responsible for their own treatment decisions. And, even if parental support is still present, a nurse or other healthcare provider is likely to answer questions and support the



self-determination of their life goals and treatment choices.

The National Cancer Institute (NCI) affirms that children cannot legally consent to clinical research protocols until the age of majority as defined by the state or locality in which treatment is sought; the majority of states have determined the legal age to be eighteen years for adulthood (NCI, 2016). Although the competence of minors and young adults to make informed medical decisions is related to both their intellect and the situations under which these skills are applied, there are circumstances, such as a cancer diagnosis, which weakens or strengthens the psychosocial attributes that could impair their decision-making (Silber, 2011). The AYA's participation in the decision-making process can also be affected by the development of several different skills such as: maturity of judgement, cognitive ability, and moral authority, which may not be at the same level for every patient (Levine, 2008; Weithorn & Campbell, 1982; McCabe, 1996). Steinberg (2013) further argues that the skills and abilities needed to make an informed choice are likely in place several years before the AYA is able to control the cognitive behaviors under emotional conditions.

Interestingly, in adolescent health behavior research, the confidentiality of adolescents and their right to agree to participate in research is essential (Brawner, et al., 2013; Olds, 2003). If adolescents could not provide their own informed consent in these situations for behavioral research, then researchers would not have the representative data source needed to plan appropriate interventions. The practice of involving children in research involves placing an emphasis on a progression of assessments that combine appreciating the child's defenselessness combined with a respect for their developing maturity (Hein, et al. 2015a; Fisher, 2003; Kodish, 2003a.). The decision of what is best

for the adolescent assumes that parents, as surrogates, are the appropriate decision-makers to determine the benefit of medical care for their adolescent. However, since the intention of research is to contribute to the development of generalizable knowledge, this means its purpose is to benefit society and not an individual (IOM, 2009; Kodish, 2003b).

Then there are longitudinal research studies. With longitudinal research, depending on the timeline, there is the possibility of studies that began in childhood and extend into adulthood. Seeking the parents' consent at the beginning of the study for the child's participation could extend their participation after they reach the age of adulthood. In this instance, the now adult participant should either re-consent to the study or decide to decline continued participation, but only if re-approached by the researcher. Therefore, there are instances when the parents have the authority to make decisions on behalf of their children that will actually extend into adulthood (Berkman, et al., 2018).

Despite the gains that have been made in treatment of pediatric malignancies, fear and anxiety still exist which have an impact on the efforts of the adolescents and young adults to cope with the many facets of a life-threatening illness. The majority of cancers diagnosed in the adolescent and young adult (AYA) have not shown the same survival progress as the younger and older patient (Keegan et al., 2016), and young adults are also less likely to carry personal health insurance plans (Parsons, et al., 2014). Although the AYA may see the treatment as beneficial, their decision to consent could be affected by the belief that the continued relationship with their physician provider depends on agreeing to participate in research, and/or that the provider or parent is acting in their best interest (Cherry, 2017; Bester et al., 2016). Hickey (2007) added that the determination of an adolescent's competence needs to include evidence that they understand the

purpose of the treatments, the risk of treatment in the short and long term, any benefits to their disease course, and the alternatives to the proposed treatment, in addition to, giving their consent to treatment without pressure from parents or others.

Accordingly, Schlam and Wood (2000) assert that the transition from incapable to capable decision-maker does not occur instantaneously upon reaching the age of majority, but instead is a process that the adolescent and young adult has participated in since the beginning of treatment choices and is a continual along the entire course of the disease and its treatment. Unrestricted, voluntary informed consent to clinical cancer research can cause anxiety in individuals who lack adequate development of all of the mental and perceptual capacities necessary to consent on their own behalf (Cherry, 2017). Furthermore, Higgins and Daly (2002) stressed that bioethical principles tend to focus on autonomy and non-maleficence rather than to tackle the challenging problem of how to assess voluntariness, assure comprehension, and safeguard vulnerable and young population. Often, the parents are dependent on the physician's support and knowledge as they do not remember much of the information presented when informed consent is obtained, or truly understand what is presented, because the complex clinical research forms and the need to make decisions are delivered when they are in highly anxious state (de Vries, et al., 2011; Ruccione, 1994). Since parents are tasked with making the decision or participating in the decision with the young adult, they want to do what is best for their child, and at the same time are fearful of making the wrong decision (de Vries, et al., 2011).

The adolescent and young adult may feel overwhelmed and alone, even in the presence of family, when protocols are discussed and informed consent obtained. Mayer

(1985) and Johansen, et al. (1991) reiterate that the nurse should remain empathetic to the patient and family's state of anxiety, and how this apprehension affects the retention of the large volume of information given during the informed consent process. Since the diagnosis of cancer can emotionally and physically impact quality of life and lessen the AYA's sense of control, this may broach issues that suppress their autonomy (Gadow, 1989a). Pediatric oncology nurses are involved in almost every part of the informed consent process, their role is to support, answer questions, and assess the knowledge and comprehension of both the patient and the family members, while recognizing their own personal biases and preferences (Rosse & Krebs, 1999).

Informed consent requires and ethicists recommend healthcare professionals to assess comprehension prior to accepting their assent or consent (Kon & Klug 2006). Because most pediatric cancers start at a young age or have pediatric origins, adolescent and young adult patients remain with their pediatric oncologists long into adulthood. Therefore, the pediatrician's ability to continue to communicate with the AYA is vitally important. As the quality of life wanes, mature adolescents and young adults want their expressed wishes about goals of care to be respected by parents and providers at the appropriate time (AAP, 2016; Katz & Webb, 2016).

Lastly, pediatric oncology nurses are aware of the here-and-now attitude of the adolescent and young adult and realize, therefore, that activities such as: school, graduation, 18th & 21st birthdays, and social relationships will all affect the young adult's decision-making processes in regards to treatment decisions (Butow, et al., 2010). In addition, the adolescent and young adult is transitioning from mostly interactions with parent to predominantly peer interactions, and these peer relationships have an

importance to them and their primary outlook on life (Hein, et al., 2015a).

## **INFORMED CONSENT STUDIES**

Although much has been written about informed consent, few studies have been conducted on children and adolescents with or without their parents. Grady, et al. (2014) conducted a study regarding research participation agreement or assent in 177 adolescents, aged 13 to 17 years, who were enrolled in cancer clinical research protocols in two highly regarded cancer institutions in the United States, along with their parents. At the time of the study, little research had been undertaken regarding the views of adolescents and their parents about the process of informed consent or the varying aspects of parental involvement in clinical research enrollment decisions. The study found that most participating adolescents believed their feelings and ideas about enrollment in a cancer research protocol mattered more or at least equal to their parents' opinions. The study suggested that the adolescents and their parents routinely made decisions together. Indeed, most adolescents surveyed perceived the assent/permission process as satisfactorily respectful to their needs and most felt they could and should sign the consent forms. Furthermore, the adolescents divulged that they trusted their parents to guide them in making important decisions, as well as, expected them to respect their choices (Grady, et al., 2014; Broome & Richards, 2003).

Koyfman et al., (2013) and Sharp (2004) both studied the readability of consent forms for cancer clinical trials. Although it was felt that these forms should be at or below an eighth grade reading level, the forms were found to be above eleventh grade reading level and very lengthy with an average length of 6 -35 pages. Between the

complicated language of the consent forms and increased number of pages, both groups of researchers deduced that it was not surprising that adults demonstrated poor comprehension. Therefore, it would follow that it would also be difficult for anxious parents and adolescent and young adult patients to comprehend lengthy consent forms with complicated medical language.

Kon and Klug (2006) analyzed responses from 102 clinician participants, both pediatric and adult, regarding whether or not they assessed comprehension or decisional capacity in patients prior to seeking consent. They found that only about two-thirds did assess comprehension with no differences among pediatric and adult participants. They concluded that assessment of both comprehension and decision making capacity should become a necessary standard to seeking validity in informed consent for all potential subject of study protocols, regardless of age, as many investigators do not ensure and document comprehension of the consent process.

Hein, et al. (2014) interviewed 161 children and adolescents between 6 to 18 years in the Netherlands utilizing the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) developed by Grisso and Applebaum (2001) and modified for children by permission with a validity study (Hein, et al., 2012). The structured 13 item interview tool assessed the decision-making abilities and competence of subjects to consent to participation in research. The tool was derived from the original instrument, the MacArthur Competence Assessment Tool for Treatment (MacCAT-T; Grisso & Applebaum, 1998). Study outcomes found that while the investigators assessed 54 children of the 161 (33.5 %) to be incompetent prior to instrument administration using standard reference; of these the MacCAT-CR found 61 children (37.9 %). These

results suggested that the MacCAT-CR scores of the four domains of adult competency: understanding, appreciation, reasoning, and choice could be condensed to a single score when utilized with children. Therefore, in children older than age twelve, seeking their informed consent could be reasonable if competence could be established on a case-by-case basis using the MacCAT-CR instrument. (Hein, et al., 2014).

Subsequently, as a follow up study, Hein, et al. (2015b) used the MacCAT-T (MacCAT for Treatment) to assess children's knowledge to consent to medical treatment, such as genetic testing. The results demonstrated that the MacCAT-T was promising for standardizing competence assessment in children that were exposed to treatment situations. In this pilot study of 17 pediatric patients between the ages of 6 and 18, the MacCAT-T considered 16 of them to have clinical judgment and competency to make treatment decisions when involved in the informed consent process. These studies by Hein, et al., using a structured interview approach in children, are among the most recent in the literature demonstrating the ability of adolescents under 18 years of age to participate in the informed consent process with the same decision-making capabilities of adults.

No previous quantitative studies of adolescent and young adult patients 16-24 years of age were found in the literature. Therefore, adult informed consent studies need to be considered to provide an overall summary of informed consent in the adolescent and young adult (AYA). The MCAT-CR was administered to 50 adults with bipolar disorder by Klein et al. (2019) and their findings suggested that certain measures of illness severity were associated with lower levels of capacity to provide informed consent. Candilis, et al. (2008) when studying a population of three categories of patients

in equal parts (n=160) schizophrenia, diabetes and non-ill subjects, again using the MCAT-CR found outcomes of cognition, education, and mental status to be important factors in decision-making capacity. However, the study indicated that future research should also consider physical and emotional functioning among different populations.

Joffe, et al. (2001b) studied a cross section of adults participating in cancer clinical trials and found that approximately 30% of them believed that the cancer protocol recommended to them to which they had consented had already been proven as the best treatment for their cancer. In a systematic review of interventions to improve adult research participants' understanding, Flory & Emmanuel (2004) suggested that research participants repeatedly did not understand information provided to them in the informed consent process, and continued creative solutions to improve the understanding of consent through the use of multimedia-enhanced forms had had limited success. More research with multimedia consent forms was needed before a positive effect on understanding could be proposed.

Coleman & Rosoff (2013) wrote that the legal scope of a mature adolescent's authority to consent to medical treatment still requires parental signature. Individual rights, including parents' rights, are determined by age of majority which is eighteen years of age. Most states do not permit even mature minors to consent to general medical care unless the adolescent has been declared emancipated by legal means; parental consent is necessary (Coleman & Rosoff, 2013). Moreover, Coleman and Rosoff (2013) recommend that healthcare providers have protection from liability when meeting the informed consent requirements as established in individual cases, as well as, maintain appropriate records concerning the maturity of the patient and parent availability and



participation in the process. Accordingly, parents can disregard an adolescent's dissenting voice and permit medical treatment in the best interest of the adolescent (Caplan, 2007). For healthcare providers, the adolescent's ability to speak rationally and make responsible decisions can change and grow as they mature, and older adolescents and young adults have similar developmental and intellectual abilities. (Coleman & Rosoff, 2013).

Kathleen Ruccione, RN (1994) reiterates that there are four components of informed consent: disclosure, comprehension, competency, and voluntariness which resulted from the *Nuremburg Code* defining informed consent as the person involved having "the legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress,...; and should have sufficient knowledge and comprehension of the elements of the subject matter involved to enable him/her to make an understanding and enlightened decision" (Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, 1949). In a qualitative study with the parents of 28 pediatric oncology patients, Ruccione found that although parents were generally pleased with the consent process, they had varying feedback and insights on how the treatment protocol was explained, and this was found to consistent with their visible anxiety and noted educational background (Ruccione, et al, 1991). Her research results maintained the patient and family suffered the repercussions when cancer treatments and potential side effects were not presented in a manner that parents could absorb, retain, and recollect when needed (Ruccione, et al., 1991). In 1994, Ruccione continued that since nurses were at the bedside providing 24/7 care and could ask follow up and clarification

questions for families, they needed to be educators for the family, while also advocating for the adolescent patient in the informed consent process.

While Hickey (2007) maintained that the determination of an adolescent's competence to assent/consent needed to include evidence that they could understand the purpose of the treatments, the risk of treatments in the short and long term, any benefits, and even the alternatives to the proposed treatment, it was most important that they gave their assent/consent to treatment without coercion.

It has become increasingly clear indicates that research participants of any age have incomplete comprehension of data specific to the research studies in which they have consented and are misinformed about the process and purpose of research (Corbie-Smith, et al., 2002; Freimuth, et al., 2001), particularly for racial and ethnic minority research participants (Quinn, et al., 2012; Sudore, et al., 2006). Barnes, et al., (1998) interviewed 31 Chinese, Latino, and Anglo-American patients regarding their beliefs about informed consent and found that the patient's culture and language impacted how much the patients understood about the treatment and protocols. Interestingly, all three groups were affected by use of subtle differences in wording and indirect expressions of language. In addition, it was discovered that patients wanted to passively accept medical decisions instead of making fully informed independent and autonomous decisions about the plan of care. Lastly, when patients did not speak the same first language it was found that the patient's recall of information was significantly lowered and using an interpreter did not always help the situation for the patient. For these patients, more time and repetition was needed, as well as, more teach back of the information. If adults demonstrate difficulty with informed consent documents and process, how much more

must the adolescent and young adult oncology patient be affected.

Joffe, et al. (2001a) developed a survey tool entitled the QuIC (Quality of Informed Consent) based on the NIH template for informed consent. During their research, they noted that adult cancer trial participants had universal problems with understanding (Lidz, et al., 2004; Joffe, et al, 2001b). Subsequently, Joffe, et al. (2001b) surveyed 207 patients from the Dana Farber Institute who were enrolled in clinical trials using a questionnaire designed to assess the usefulness of the National Cancer Institute template and their providers. They found that 90% or 186 of these respondents considered themselves to be well informed and satisfied with the informed consent process. However, the results of research found that participants did not recognize nonstandard treatment (74%), risks of participation (63%), unproven nature of treatment (70%), uncertainty of benefits to self (29%), or (25%) that clinical phase I trials were undertaken to benefit future patients (Joffe, 2001b). The lowest scores on the survey were associated with less than a college education and the use of a language at home other than English. Joffe, et al. (2001b) concluded that several simple interventions, such as: the use of a structured consent template, the presence of a nurse, careful reading of the forms, and not signing it at the initial meeting all increased the study participants' knowledge. As an incidental finding, only 28 of 61 providers queried (46%) recognized the main reason for clinical trials is to benefit future patients (Joffe, et al. 2001b).

Poston (2016) used the QuIC in her pilot descriptive mixed-methods study of a small group of adolescents, their parents, and their physicians and found that the participants had a reduced level of understanding of main elements of informed consent and assent on the objective portion of the survey compared to the subjective portion and

self-reported poor recollection of some of the key details of the informed consent and assent discussion. She concluded that the study participants built a relationship of trust in their providers that guided them through the clinical trial and more research needed to be done regarding informed consent.

Broome and Richards (2003) conducted a qualitative study of 34 children and adolescent study participants utilizing a semi-structured interview to explore the children and adolescents' understanding of clinical research and sociocultural factors that influenced their decisions. They concluded that three themes emerged from the data that affected the decision making process of the children: faith in their parents, rapport with the research team, and consequences of disagreement with parents' decisions (Broome & Richards, 2003). Sibley, et al., (2018) conducted a two stage study of 239 pediatric patients and their parents to explore the decision making power and ability of the child within the family as the child matured. The researchers concluded that none of the pediatric patients desired to make all decisions themselves, but that they trusted their parents to make good decisions for them, and appeared to understand their place in the familial hierarchy. In addition, the parents proposed that their children were capable of making some decisions, but felt that children wanted some input from their parents. The parents also expressed a desire to guide the decision making without strict enforcement.

Beadle, et al. (2011) studied oncology nurses regarding their perceptions of ethical issues relevant to cancer clinical trials. Using an investigator-designed tool, the researchers found that oncology nurses had perceptions of patients' understanding, knowledge, and willingness to participate in cancer clinical trials, in addition to the informed consent process, and patients' health and safety. The Likert scale 50 item

assessment tool consisted of six parts: understanding of clinical trials, informed consent, participant welfare, willingness of subjects to participate, personal perception of vulnerability, and benefit to society of clinical trial research (Beadle, et. al, 2011). The results of the study suggested that oncology nurses have a good understanding of the ethical considerations of cancer research and can provide valid experiences of the daily conduct of clinical trials, as well as, provide potentially important insights into the application of ethical ideas (Beadle, et. al, 2011). All of the prior research concludes that there is much to be done to ensure the quality and understanding of informed consent in all age groups, and certainly the adolescent and young adult patient is a knowing participant to the process.

## **NURSING ADVOCACY STUDIES**

Bu and Jezewski (2007) examined the concepts of advocacy in nursing literature with a systematic review and concluded that there were three core attributes which included “safeguarding patients’ autonomy, acting on patients' behalf, and supporting social justice while providing health care” (p.104). This led to the development of the APAS (Attitude towards Patient Advocacy Scale), a 64 item Likert scale instrument with three subscales to align with the three core concepts. The APAS was administered to two sample groups of oncology nurses to validate psychometric properties (Bu & Wu, 2007). Barrett-Sheridan (2009) utilized the APAS in her dissertation research to study the association between the political behaviors of nurses and attitudes of nurses to advocate for patients at the macro-social level. The study suggested that a barrier exists between the positive attitudes of nurses toward macro-social patient advocacy and acting on the needed political behaviors by nurses to accomplish patient advocacy goals (Barrett-Sheridan, 2009).

Abbaszadeh et al. (2013) studied Iranian nurses and asserted that the nurses are advocates because nursing builds relationships with patients within healthcare and are involved in direct patient care. They further confirmed that since nurses provide frontline care to patients within hospital networks, this affords them the opportunity for advocacy. Their findings also indicated that the older, experienced nurse advocated for patients more than the younger, inexperienced nurse. (Abbaszadeh, et al., 2013). In a further qualitative study, Davoodvand, et al. (2016) examined the viewpoint and experiences of 15 Iranian clinical nurses and found that patient advocacy consisted of empathy with the patient and protecting the patients. Other advocacy studies revealed nurses utilize their professional knowledge to interceded on behalf of patients with actions of fighting, speaking, and standing up for patients (Choi, 2015; Hanks, 2008; Chafey, et al., 1998) or acting as the patient's voice (Davoodvand, et al., 2016; Haylock, 2015; Kalaitzidis & Jewel, 2015; Hank, 2008; Foley, et al., 2000). Nonetheless, Black (2011) cautioned that nurses, as employees of hospitals, were in a precarious position to advocate. Accordingly, nurses might not advocate due to fear of losing their jobs (Black, 2011), or if doing so caused them moral or emotional distress (Ramos, et al., 2018).

Several other qualitative research investigations are available in the patient advocacy literature. In 2005, O'Connor and Kelly found when studying nurses in Ireland, the primary role of the nurse advocate was as liaison between the patient and the health care environment. Their results also highlighted that advocacy could result in conflict and confrontation with others that could be damaging, both personally and professionally, to the involved nurses (O'Conner & Kelly, 2005). Chafey, et al. (1998) interviewed 17 nurses in three sites in Montana and found that advocacy occurred when patients could not express their own needs, had a nurse with the traits to support advocacy, and had an environment conducive to advocacy. Toda, et al. (2015) similarly interviewed 21 mental health nurses in Japan with 5 or more years' experience and found that although nurses

sought harmony as per Japanese tradition, they would protect patients' rights against the cultural norms based on respect, but they first sought solutions suitable to the cultural norms before any other solutions (Toda, et al., 2015).

Hanks (2008) conducted a doctoral research to validate psychometric properties for the Protective Nursing Advocacy Scale (PNAS) using a study sample of 419 medical-surgical registered nurses in Texas. According to Hanks (2008), the Protective Nursing Advocacy Scale (PNAS) measures the presence of nursing advocacy behaviors in the health care environment from the perspective of protecting patients. More specifically, it looks at beliefs and action behaviors of nurses to protect or advocate for patients. Hanks developed his 38-item Likert Scale to quantify the nurse's advocacy actions after an exhaustive review of literature that found mostly qualitative research describing the essence and meaning of nursing advocacy from the perspective of nurses. Hanks concluded that there was a need for a reliable and valid measurement of nursing advocacy. He ascertained that the results of the study could improve the quality of nursing advocacy along with other safety initiatives as the PNAS instrument provided a specific measure of protective nursing advocacy beliefs and actions (Hanks, 2010). Hanks (2010) further surmised that using the PNAS in continuing education programs could increase an awareness of advocacy actions and beliefs in currently practicing nurses that could positively impact patient outcomes and lead to increasingly effective advocacy.

Thacker (2008) also felt that educational exposure to nursing advocacy behaviors helped increase the quality of end-of-life care. The study employed a descriptive design which compared the differences among novice, experienced, and expert nurses about their perceptions of advocacy behaviors. Thacker (2008) found in this study no significant differences between the perceptions of patient advocacy and the experience levels of the nurses surveyed. However, the results did show a significant difference

between nurses who had participated in educational programs compared to those nurses who had not been trained in advocacy (Thacker, 2008). Like Hanks, Thacker concluded that formal advocacy education was fundamental to the implementation of advocacy behaviors in nursing practice. Hewitt (2002) wrote that before nurses could empower patients, they needed to be empowered first to do so.

While exploring Swedish nurses' perceptions of influencers on patient advocacy, Josse-Eklund, et al. (2014) interviewed 18 nurses using phenomenology as the research design. They found that influencers on patient advocacy exist on three levels: the nurses' own character traits, the bond with the patient, and the organizational conditions that create the surroundings where the nurses work. The study's results suggest that the primary agent of patient advocacy is the patients' unmet or unconsidered needs. Therefore, nurses need to be accustomed with their patients and their conditions to be confident and comfortable to advocate for patients (Josse-Eklund, et al., 2014). All of the studies provide insight on the importance of nursing advocacy behaviors in the provision of patient care.

## **SUMMARY OF LITERATURE**

In summary, although informed consent is a necessary component of the clinical trial process, limited studies have addressed issues related to the adolescent and young adult population. While there are numerous studies related to informed consent with adults and parental decision-making for children as well as pediatric assent and none have examined the ability of adolescent and young adult oncology patients to fully comprehend the impact of their decision to participate in clinical trials, nor have any studied the pediatric oncology nurses' roles in the process. In addition, the present body



of nursing advocacy literature has concentrated on mostly qualitative studies of nurses' beliefs of advocacy behaviors, each with small numbers of participants. Although those studies focused on advocacy in nursing specialties in various countries, most utilized semi-structured interviews and self-report. Although few quantitative studies explored nursing advocacy behaviors, this current study was the first to explore advocacy behaviors of pediatric nurses who care for adolescent and young adult patients in a variety of clinical settings who were faced with informed consent decisions related to cancer clinical trials. Collectively, past studies have not addressed both issues of informed consent and nursing advocacy behaviors together in one study. There is a need for ongoing research related to the ethical and potential legal issues in the informed consent process with this vulnerable group of adolescent and young adult patients, as well as additional research which addresses differential knowledge and advocacy responses of both inexperienced and experienced nurses.

## **CHAPTER 3: RESEARCH DESIGN AND METHODOLOGY**

### **INTRODUCTION**

This chapter identifies the research design, and describes the recruitment, sampling methods, and data collection methods. It also establishes the study setting and inclusion/exclusion criteria, discusses the study tools, and presents the limitations and ethical considerations relevant to human subject participation. It concludes with the explanation of the data analysis procedures.

### **RESEARCH DESIGN**

A descriptive, exploratory research design was used for this study. An exploratory research design is used when the researcher wants to investigate the relationship among two or more variables. This approach predicts the effect of one variable on another and tests the relationships between variables or population demographics supported by clinical theory (Portney & Watkins, 2009, p. 277). A descriptive research methodology was used to identify and describe the perceptions of pediatric oncology nurses and advocacy responses to ethical issues in securing informed consent in adolescent and young adult patients. Furthermore, it sought to describe the relationship between the numbers of years of nursing experience and how informed consent and advocacy was perceived by pediatric oncology nurses caring for the adolescent and young adult. This type of research design was specified because it allows data collection without the introduction of an intervention or treatment (Polit & Beck, 2014).

## **SAMPLE, SETTING AND RECRUITMENT**

The study sample consisted of 270 pediatric oncology registered nurses living in the United States currently working full or part-time providing direct care for adolescent and young adult pediatric oncology patients. Participants with an email account were able to access the survey via a recruitment email with a corresponding Survey Monkey© link. Each participant was able to complete the survey in any location of their choosing, at any time of day, and could return to the survey until it was completed and submitted. Additionally, the sample consisted of voluntary participants using purposive sampling design techniques, creating a specific sample of pediatric oncology nurses and nurse practitioners for inclusion in this study. Survey participants were recruited from the membership roster of the Association of Pediatric Hematology/Oncology Nurses (APHON), an international association with about 3,000 members, snowballing of participants from contacts at previous employers, oncology units at a Fort Worth Children's Hospital, and sample emailing lists from online database services specializing in healthcare marketing and research. The Email Recruitment Letter is included in Appendix D.

## **INCLUSION CRITERIA**

Inclusion criteria for participation were nurses currently working full or part-time caring for adolescent and young adult pediatric oncology patients in the U.S. To be included in the sample population, these pediatric oncology nurses were at least 21 years of age, able to read and understand the English language, had access to the internet, and were employed and worked for at least six months as a nurse.

## **EXCLUSION CRITERIA**

Exclusion criteria for participation in the study were nurses currently practicing outside the United States or caring for patients other than pediatric oncology patients. Also, excluded were pediatric oncology nurses who could not read nor understand the English language. Currently unemployed or retired nurses formerly caring for pediatric oncology patients were also excluded. In addition, the study excluded pediatric oncology nurses who did not have access to the internet, were younger than 21 years of age, and/or had been employed or had worked for less than six months as a nurse.

## **DATA COLLECTION**

Data collection began on July 14, 2019 and ended on February 8, 2020. The data collection process consisted of 3061 individually sent recruitment emails, containing a Survey Monkey link to the questionnaire which included the demographic data questions, the PNAS (Protective Nursing Advocacy Scale) and the NEQ (Nurse Ethics Questionnaire) instruments. The recruitment email provided a brief explanation of the proposed research, and invited each pediatric oncology nurse to participate in the study. It also provided informed consent and protection of subjects' information, described the time requirements to complete the survey, and furnished the researcher's contact information, along with UTMB IRB protection language (Appendix D).

The survey data was collected by Survey Monkey®, an online survey database company. A reminder email was sent from Survey Monkey one week after the initial email invitation. A second reminder email was sent by Survey Money to all potential

participants on October 20, 2019 with a response rate of 30 more responses. On November 26, a reminder email was sent to the 60 participants who had partially completed the survey at that time with completion of 3 more surveys. A final reminder email was sent on December 14, 2019 to 1167 of the recipients who had opened the email link but not yet responded. Of the initial 3000 emails sent, 1817 of the emails reached their destination and were opened, 1154 individual emails were never opened or went to junk or spam mail, 20 emails bounced as inaccurate or no longer valid email addresses, 380 at least reviewed the survey email inquiry, and 70 people opted out of Survey Monkey © emails. The overall email survey response rate was 332; of these returned surveys 270 were complete for the NEQ instrument, 260 for the PNAS, and 62 were partially complete or had missing data points and had to be removed for data analyses. A conservative power analysis for the study recommended a minimum sample size of 318 from the initial population size of 1817 opened email inquiries using a response distribution of 50%, a 95% confidence level and a 5% margin of error on the Raosoft sample size calculator (Raosoft.com, 2018).

## **DATA MANAGEMENT**

As data was collected, it was stored as part of Survey Monkey's © secure database then downloaded, cleaned and transferred to an excel file on a password protected laptop. It was then entered into a separate dataset using data analysis software IBM SPSS Statistics for Windows (v. 26). The data were evaluated for completeness and secured within a password protected laptop, as well as, backed up with a password protected flash drive at the primary investigator's home office. Completed surveys were

printed out and collected and stored in a locked cabinet in the primary investigator's home office. Original surveys were randomly compared to the completed dataset and validated for completeness. The narrative responses to the single narrative question regarding an example situation were transcribed by the researcher and stored in a separate Microsoft Word document identified only by a participant code.

## **INSTRUMENTATION**

This study utilized two instruments and a bio-demographic data sheet, as well as, a single narrative response question. The first instrument was the Nursing Ethics Questionnaire (NEQ) developed by Beadle, et al. (2011). The second was the Protective Nursing Advocacy Scale (PNAS) developed by Hanks (2008) in his dissertation research and copyrighted by Sage Publications (2010). The demographic data information sheet was created by Beadle, et al. (2011) and adapted for the sample population of the Pediatric Oncology Nurse. A single, optional narrative response question was included at the end of the survey that stated: Describe in detail, as much as you can remember, an experience of the informed consent process and/or an experience of a situation when you were called upon to be a nurse advocate involving an adolescent and young adult oncology patient participating in a cancer clinical trial.

## **DEMOGRAPHIC SURVEY**

Demographic data was obtained from the pediatric oncology nurse participants through the use of demographic questions from the Demographic Data Information Sheet modified specifically for this research study (Appendix A). It collected the following

information: age in years, years of nursing experience, gender, ethnicity (White/Caucasian, Hispanic/Non-White, Black/African American, Asian/Pacific Islander, American Indian/Alaskan Native), education - the highest nursing degree (Diploma, Associate's Degree, Bachelor's Degree, Master's Degree, Doctoral Degree), type of work setting (Teaching hospital, Non-teaching Hospital, Outpatient Clinic), and field of nursing (Patient care, Education, Administration, Clinical Research). It also asked the participants several questions related to their work setting regarding the adolescent and young adult oncology patient population. Age and work status were also used as screening variables to assure participants met the inclusion/exclusion criteria.

#### **NURSING ETHICS QUESTIONNAIRE (NEQ)**

This questionnaire is an investigator-developed tool designed to gain an assessment of oncology nurses' perceptions of whether ethical research ideals were encountered in the daily conduct of cancer clinical trials (Beadle, et. al, 2011). Cronbach's alpha for the entire scale was 0.74. It was designed to evaluate six different domains of cancer clinical trials: nurses' perception of the reasons patients participate (NEQ-1: Decision-Making – 9 items) and their knowledge (NEQ-5: Patient Knowledge - 6 items), the perception of the care patients receive (NEQ-2: Patient Care), and the perception of the informed consent process (NEQ-4: Informed Consent – 13 items), the general nurses' attitudes towards and the value of clinical trials (NEQ-3: Attitudes Toward Clinical Trials), as well as, the nurse's level of participation in clinical trials (NEQ-6: Participation).

The tool was first adapted after compiling a series of ethical questions and statements from an extensive literature review which was then evaluated by a focus group of six oncology nurses with varied experience for item clarity, evaluation of relevance, and response options, and then the items were modified according to the feedback (Beadle, et. al, 2011). The first three domains assessed the nurses' experiences of cancer clinical trials relevant to trial participation and the fourth domain assessed the perceptions of the patient's willingness to participate in cancer clinical trials. Response options to items in each of these subscales were *all of the time, most of the time, some of the time, rarely, never, and don't know*. The remaining two domains assessed the nurses' personal perceptions of the vulnerability of potential research subjects and the societal benefits of cancer clinical trials. For items in these two domains, the response options were *strongly agree, agree, unsure, disagree, strongly disagree, and don't know*. Scores for each item of the subscale were added together to provide summated subscale scores for each of the six parts to the questionnaire and a total scale score.

The NEQ was administered to a random sample of two-thirds the nursing membership of the Cancer Nurses Society of Australia who worked with physicians, researchers, and adult oncology patients participating in all phases of cancer clinical trials (I, II, and III). The results of this study demonstrated that oncology nurses did have opinions about the ethical constructs associated with how cancer clinical trials were conducted generating the need for further investigation to explore the ideals of ethical research and development of the NEQ instrument (Beadle, et al., 2011).

For the purposes of this study only the NEQ-1: Decision-Making (9 items), NEQ-4: Informed Consent (13 items), and NEQ-5: Patient Knowledge (6 items) were utilized



to assess the perception of the pediatric oncology nurse as to the patients' decision to participate in cancer clinical trials, informed consent, and knowledge of the clinical trials. The Cronbach's alpha for the NEQ-1 subscale was reported as .75, for the NEQ-4 as .76, and for the NEQ-5 as .74. Response options to items in each of these three subscales were according to a Likert scale of *all of the time*, *most of the time*, *some of the time*, *rarely*, *never*, and *don't know*. Totals for the subscales were added together to achieve a summative total scale score. Low total scores on the NEQ were the desirable outcome, indicating the item responses were present all of the time, with a total score range of 28 to 140, with *don't know* scored as a 0. Percentages of each item within each subscale were also assessed for overall knowledge of the subscale's concept. The NEQ instrument had not been involved in any further studies according to the authors and permission to use the instrument for this research was granted by Dr. Geoffrey Beadle and Patricia Yates, RN, Queensland, Australia. The NEQ instrument and its instructions are included in Appendix B.

#### **PROTECTIVE NURSING ADVOCACY SCALE (PNAS)**

The Protective Nursing Advocacy Scale (PNAS) was copyrighted, following dissertation research by Dr. Robert Hanks in 2008, utilizing medical surgical nurses in Texas. It was developed to provide a quantitative measure of nursing advocacy beliefs and actions from the patient protection perspective (Hanks, 2010). The reliability for the entire PNAS instrument, calculated by Cronbach's alpha from the research, was .803. In addition, the four subscales have reliabilities ranging from .70-.93 and are as follows: PNAS-1: Acting as Advocate consisting of 16 items - .91, PNAS-2: Work Status and

Advocacy Actions consisting of 5 items - .93, PNAS-3: Environment and Educational Influences consisting of 8 items - .73, and PNAS-4: Support and Barriers to Advocacy consisting of 8 items - .70. Content validity was evaluated using a panel of eight medical surgical nursing experts that rated content relevance of items to the constructs being measured using a Likert Scale and the index for this was 0.79 (Hanks, 2008).

The final PNAS instrument consisted of a 38-item questionnaire utilizing a Likert Scale with response options of *strongly disagree*, *moderately disagree*, *neither agree nor disagree*, *moderately agree*, and *strongly agree*. The totals for each subscale are added together for a summative final scale score. For the purpose of this research, two subscales of the PNAS instrument were utilized, and these were the PNAS-1: Acting as Advocate, where the 16 items reflect education and experience as influential on the ability to advocate, and PNAS-2: Work Status and Advocacy Actions, where the 5 items reflect the interaction between advocacy and the workplace setting (Hanks, 2010). For the PNAS-1 the desirable outcome was a high score, and for the PNAS-2 the desirable score was low. The scale scores ranged from 16 to 105. In order to utilize the PNAS instrument for this research, Dr. Robert Hanks was asked, and Sage Publications granted permission to use the copyrighted instrument. The PNAS instrument and its instructions are included in Appendix C.

## **PROTECTION OF HUMAN SUBJECTS**

The University of Texas Medical Branch Institutional Review Board (IRB) gave permission to conduct this study. (Appendix E). All data collected remained confidential and anonymous. Completed questionnaires were stored in a password protected database

accessible on a password secured laptop. Participants were able to answer the survey tool questions using a computer at a location and time of their choosing. Prior to accessing and completing the survey questions, participants were instructed that opening and completing the survey indicated their consent to participate. Average time to complete the survey was 7 minutes. In addition, participants were informed in the recruitment email that study participation was voluntary, and they could withdraw at any time by simply not completing the electronic survey or not submitting the link at the end of the questionnaire.

Participants were provided with contact information for the researcher in the recruitment email, and submitted individual responses to the survey were not linked to any email addresses or other identifying information. No participant was denied involvement in the research study based on gender, age, ethnicity, religion, sexual orientation, or educational status. Email addresses were the only identifying contact mode of communication and were not associated with any names or locations.

## **LIMITATIONS AND ASSUMPTIONS**

The research study was affected by several limitations. The first was the use of email addresses as the method of invitation to participate which was affected by server firewalls, spam settings, and the overall email security utilized by organizations and individuals to protect the integrity of the email server. The study was also limited to available email addresses either by specialty association directory membership, snowballing purposive sampling, or marketing email sample lists. Therefore, not all eligible, currently employed, pediatric oncology nurses in the United States email

addresses were accessible to the researcher for participation. Moreover, not all nurses who opened the survey completed it, and those who did open the email may not have met the eligibility requirements. The subjects who voluntarily agreed to participate may not have been representative of the general population of pediatric oncology nurses. The interpretation of the findings was limited to the participating subjects at the period of time that data collection occurred. The ability to generalize the results of the current study could have been limited by the relatively small sample size and small number of inexperienced nurses in the overall sample, as well as, the overrepresentation of Caucasian, highly educated, older, and experienced oncology nurses. In addition, there were several assumptions applicable to the current study. The researcher assumed nurses provided truthful and accurate responses to the survey according to their knowledge of the subject at the time they completed the survey. The items on the subscales were assumed appropriate to measure the study variables. The researcher assumed that those who answered the survey tools valued the role of patient advocacy in nursing, had knowledge of and participated in the informed consent process with adolescent and young adult oncology patients, and were familiar with experimental cancer clinical trials.

## **DATA ANALYSIS**

In this descriptive, exploratory research design, pediatric oncology nurses from across the U.S. completed the online study survey, which included the Nursing Ethics Questionnaire (NEQ), the Protective Nursing Advocacy Scale (PNAS), a single narrative question, and the Demographic Data Information Sheet. The IBM Statistical Package for Social Sciences (SPSS) version 26.0 was utilized for the purposes of scoring, statistical

analyses, and comparison of results. All data was entered as received and then examined for systematic missing data. Data was analyzed using descriptive statistics which included measures of central tendency, interquartile ranges, analysis of variance, standard deviations, tests of differences (i.e., independent samples t test), Pearson's ( $r$ ), and partial correlations as needed. A statistical significance of  $p < .05$  was the standard used for this research. Preliminary analyses addressed subscale and total instrument reliability using Cronbach's alpha, a measure of internal consistency, and validity using Exploratory Factor Analysis, Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy, and Bartlett's Test of Sphericity for each of the dependent variables to ensure adequate reliability and validity for subsequent analyses. All of the data were scrutinized for normality and homogeneity of variance to support if the observed differences were enough to be meaningful to the data. Standard descriptive statistics were used to describe the distribution of scores for each subscale.

The years of nursing experience were assessed as both a continuous variable and a dichotomous variable (5 or less years and more than 5 years) using the t test for differences in the means or mean ranks of the study's scales and subscale scores. The independent or unpaired t test is used to compare the means of two groups and can be used even with unequal numbers for each group (Portney & Watkins, 2009). Pearson's correlation was utilized to address the relationship between years of nursing experience as continuous variable with the three subscales of the NEQ and the two subscales of the PNAS. The correlation coefficient result can range from -1 to +1, with -1 indicating a perfect negative correlation, +1 indicating a perfect positive correlation, and zero (0) indicating no correlation at all (Portney & Watkins, 2009). Since the NEQ instrument

included a response category of *don't know*, during analyses this response category was coded as a zero (0), so as not to affect the mean score of either the subscales or total score of the instrument.

The collection of narrative responses to the single optional question was reviewed and analyzed utilizing Naturalistic Inquiry to describe and interpret the written experiences and actions of pediatric oncology nurses in their own words engaging in the informed consent process or utilizing nursing advocacy behaviors with adolescent and young adult pediatric oncology patients (Lincoln & Guba, 1985). The Specific Aims and Research Questions were analyzed as described below:

Aim 1: Research Question 1.1 was answered using descriptive statistics (means, interquartile ranges, medians, frequency distributions and skewness) to compute for the adequacy of the Informed Consent process. Descriptive statistics were used to present the distribution of scores for each subscale to illustrate the shape, central tendency and variability within a set of data to define a population (Portney & Watkins, 2009). In addition, numbers and percentages of responses to each item of the subscales were reported. Research Question 2.1 used Pearson's Correlation to explore the relationship between years of nursing experience and the revised NEQ subscales 1, 4 and 5.

Aim 2: Research Question 2.1 was answered using standard descriptive statistics to present the distribution of responses for PNAS subscale 1 and 2. Descriptive statistics were used to propose the distribution of scores for each subscale to characterize the shape, central tendency and variability within the set of data to refer to a population (Portney & Watkins, 2009). Research Question 2.2 was answered using Pearson

correlation, to explore the relationship between years of nursing experience and the PNAS subscales 1 and 2.

Aim 3: Research Question 3.1 was answered using Pearson's correlation analyses to explore the relationship between the PNAS subscales 1 and 2 and the revised NEQ subscales 1, 4 and 5. Research Question 3.2 was answered using partial correlation analyses to explore the relationship between the PNAS subscales 1 and 2 and the revised NEQ subscales 1, 4 and 5 while controlling for years of experience. The results of the preliminary and final analyses are presented in Chapter 4.

## **CHAPTER 4: RESULTS AND FINDINGS**

### **INTRODUCTION**

Chapter four presents the results of the study including the pediatric oncology nurses' demographic characteristics, the descriptive psychometric results for the study sample, and the analysis and results for each research question. The chapter also includes the compiled responses to the single narrative question related to the participant's personal experience with either the informed consent process or a situation of nursing advocacy while caring for an AYA patient.

The study had one purpose and three aims. The purpose of the study was to explore pediatric oncology nurses' perceptions of ethical issues that may arise in the process of obtaining informed consent in 16-24 year old adolescent and young adult patients who participate in experimental cancer clinical trials, and to examine if nurses engage in advocacy behaviors on behalf of these patients. The three aims of the study were as follows: 1). to explore pediatric oncology nurses' perceptions of ethical issues related to the process of obtaining informed consent in 16-24 year old adolescent and young adult oncology patients enrolled in experimental cancer clinical trials, 2). to explore pediatric oncology nurses' perceptions about advocacy behaviors regarding 16-24 year old adolescent and young adult oncology patients enrolled in experimental cancer clinical trials, and 3). to examine if pediatric oncology nurses' protective advocacy skills and behaviors are related to perceptions of ethical issues that may arise in the process of obtaining adequate and fully understood informed consent in the care of 16-24 year old adolescent and young adult oncology patients, and whether their years of nursing



experience affect this relationship. The chapter will conclude with a summation of the research study findings.

## **PEDIATRIC ONCOLOGY NURSES DEMOGRAPHIC CHARACTERISTICS**

A final sample of 270 pediatric oncology nurses recruited via the email link completed the demographic survey and NEQ instrument (n=270). From a total of 332 returned surveys, 62 of them had to be removed from data analysis completely related to incompleteness, and 10 more for analysis of the PNAS (n = 260). The resultant sample (270) was largely White/Caucasian (86%) and female (98%). The age of the participants ranged from 23 to 75 years, with a mean age of 44.7 years (sd=11.6). The majority of nurses (47%) had a bachelor's degree and 39% also held a Master's degree. The sample population had more than 42% of the participants with over 20 years of nursing experience. The years of oncology nursing experience ranged from 1 to 44 years, with a mean of 16.4 years (sd=10.43). Furthermore, the work setting was largely in a teaching hospital (61%) and most nurses were involved in patient care (73%).

The majority of respondents had adolescent and young adult patients (AYA) in their work setting that participated in cancer clinical trials (97%). For 99 % of those who responded, the adolescent and young adult patients comprised from 1 to greater than 50% of the total amount of patients participating in clinical trials in the work setting.

Additionally, 85% of the nurses answered that providing care to the AYA patient required anywhere from 1 to 50% of their daily work time. More than half (54%) held a specialty certification as an Oncology (OCN) or Pediatric Oncology (APHON) nurse. Completed surveys were returned from 43 states in the United States with Texas (38) and California (36) having the most representation, followed by Florida (15), New York (12), and Georgia (11). Demographic information for the sample population is presented in Table 4.1.

**Table 4.1: Demographic Characteristics of Pediatric Oncology Nurse Sample**

<b>N=270</b>	<b>Minimum</b>	<b>Maximum</b>	<b>Mean</b>	<b>s.d. (σ)</b>
<b>Age</b>	23	75	44.70	11.60
<b>Years in Nursing</b>	1	55	19.92	11.74
<b>Years in Oncology Nursing</b>	1	44	16.41	10.43
<b>Variable</b>	<b>Value</b>	<b>Frequency</b>	<b>Percent</b>	
<b>Gender</b>	1 = Male	6	2	
	2 = Female	264	98	
<b>Ethnicity</b>	1 = White/Caucasian	233	86	
	2 = Non-White	37	14	
<b>Highest Nursing Degree</b>	1 = Associate's Degree	11	4	
	2 = Bachelor's Degree	128	47	
	3 = Master's Degree	105	39	
	4 = Doctorate	20	8	
	5 = Other	6	2	
<b>Nursing Certification</b>	1 = ONC	8	3	
	2 = APHON	138	51	
	3 = Not Currently Certified	26	10	
	4 = Other	98	36	
<b>Work Setting</b>	1 = Hospital – Teaching	165	61	
	2 = Hospital – Non-Teaching	14	5	
	3 = Outpatient Clinic	76	28	
	4 = Other	15	6	
<b>Field of Nursing</b>	1 = Patient Care	197	73	
	2 = Education	23	9	
	3 = Administration	14	5	
	4 = Clinical Research	17	6	
	5 = Other	19	7	
<b>Do AYAs participate in clinical trials at your work setting?</b>	1= Yes	262	97	
	2 = No	8	3	
<b>Percentage of AYA patients in clinical trials at your work setting?</b>	1 = 0%	1	<1	
	2 = 1-25%	113	42	
	3 = 26-50%	86	32	
	4 = >50%	69	26	
	5 = Not applicable (not involved in clinical care)	1	<1	
<b>Percentage of work time devoted to care of AYA patients</b>	1 = 0	4	2	
	2 = 1-25%	112	42	
	3 = 26 – 50%	111	41	
	4 = > 50%	43	16	

To analyze if any of the demographic characteristics (other than years of nursing experience) would influence the research findings, statistical tests were performed to ascertain the relationship between the demographic variables and both the total NEQ score and subscales and the total PNAS score and its subscales. Correlational analysis using Pearson's correlations were performed on the relationship between age, and the PNAS, NEQ, and their subscales. Tests of differences were utilized to explore ethnic and educational group differences on the PNAS, NEQ, and their subscales. Since the sample only included six males, analysis was inappropriate for gender.

Group demographic difference analyses (Whitney-Mann U test, ANOVA) resulted in no significant difference ( $p < .05$ ) for ethnicity or highest education in either total scales or subscales. For the demographic of age and years in oncology nursing, there was also no significant difference ( $p < .05$ ) for both of the scales and subscales. There was a significant difference in years of nursing to years in oncology nursing ( $r = .810$ ,  $p = .000$ ) since these two demographics mirror nearly the same demographic, as nurses who choose oncology appear to stay with the same specialty for their career. For the purposes of this study, the years of nursing experience demographic data was utilized. The Pearson's Correlations for age and years in oncology nursing are presented in Table 4.2.

**Table 4.2: Pearson's Correlations of Demographic Data**

		NEQ-1	NEQ-4	NEQ-5	NEQ Total	PNAS-1	PNAS-2	PNAS Total
<b>Age</b>	Pearson	-.031	-.029	-.081	-.053	-.057	.073	-.018
	Sig. (2-tailed)	.616	.641	.184	.382	.360	.242	.770
<b>Yrs Onc Nurs</b>	Pearson	.111	.047	-.049	.054	.076	-.059	.042
	Sig. (2-tailed)	.068	.446	.427	.374	.219	.344	.500

## INTERNAL CONSISTENCY AND VALIDITY FOR INSTRUMENTS

The reliability index for internal consistency was addressed for the two instruments: Nursing Ethics Questionnaire (NEQ) and Protective Nursing Advocacy Scale (PNAS). Internal consistency is a measurement of the correlation of the items in the scale to each other and to the total score (Portney & Watkins, 2009, p. 606) utilizing Cronbach's alpha. DeVellis (2017) cites the following criteria as his "personal comfort zone" for research scales: between .65 and .70, minimally acceptable; between .70 and .80, respectable; between .80 and .90, very good; and much above .90, results in thoughts to shorten the scale (DeVellis, 2017, p.145). Nunnally and Bernstein (1994) and Pedhazur and Schmelkin (1991) both also addressed the standards of reliability as values of .70 and above will suffice.

Beadle, et al. (2011) reported the Cronbach's alpha for the NEQ-1 subscale as .75, for the NEQ-4 as .76, for the NEQ-5 as .74 and for the overall NEQ scale as .74. In this study, both the NEQ-1 and NEQ-5 had a Cronbach's alpha within the acceptable range of .70 - .79, while NEQ-4 and the overall NEQ were in the good range of .80 - .89.

Hanks (2008) reported Cronbach's alphas for PNAS subscales (1 & 2) at .91 and .93, respectively, and for the entire instrument when utilizing all four subscales as .803. For this study, Cronbach's alphas for PNAS subscales, PNAS-1 and PNAS-2 (.90 and .94, respectively), and overall PNAS score (.86) were in the high/excellent range.

Therefore, for this research, the NEQ and PNAS scales and subscales have internal consistencies adequate for the research study. As can be seen in Table 4.3, the Cronbach's alphas have stayed in the same range relatively for this research for each of the subscales of the NEQ and PNAS, as the authors who developed the two scales previously reported, with both of the overall scales' Cronbach's alphas slightly higher.

**Table 4.3: Cronbach's alpha for Instruments and Subscales**

<b>NEQ (Nursing Ethics Questionnaire)</b>	<b>Cronbach's alpha Subscales</b>	<b>Cronbach's Alpha Overall</b>
NEQ-1 Decision Making (9 items)	0.78	
NEQ-4 Informed Consent (13 items)	0.82	
NEQ-5 Patient Knowledge (6 items)	0.74	
NEQ Scale (1,4, &5) -Overall		0.89
<b>PNAS (Protective Nursing Advocacy Scale)</b>	<b>Cronbach's Alpha Subscale</b>	<b>Cronbach's Alpha Overall</b>
PNAS-1 Acting as an Advocate (16 items)	0.90	
PNAS-2 Work Status and Advocacy Actions (5 items)	0.94	
PNAS Scale -Overall		0.86

**PRELIMINARY ANALYSES**

Each study is a validity study and the instruments need to be validated in addition to being assessed for reliability. The approach of choice is exploratory factor analysis to assess whether the subscale dimensions are distinctly separate. To test the suitability of the data set for an exploratory factor analysis, the Kaiser-Meyer-Olkin measure of sampling adequacy (KMO) and Bartlett's Test of Sphericity were undertaken. The KMO results validated that the data set was appropriate for factor analysis and are presented in Table 4.4. The preliminary exploratory factor analyses using principle components analysis and scree plots for both instruments were conducted. The results of the preliminary factor analyses for the NEQ and the PNAS are presented in Appendices F and G.

**Table 4.4: KMO and Bartlett's Test for Instruments**

		NEQ	PNAS
<b>Kaiser-Meyer-Olkin Measure of Sampling Adequacy</b>		.881	.893
<b>Bartlett's Test of Sphericity</b>	Approx. Chi-Square	2868.83	3304.23
	Df	378	210
	Significance	.000	.000

For the NEQ, the exploratory factor analysis (FA) recovered seven factors using the eigenvalue  $> 1.0$  rule with three major factors (which matches the instrument proposed structure) and several small subfactors (4-7). The results of the initial exploratory factor analysis for the NEQ can be found in Appendix F. The results supported rerunning the factor analysis as a Forced FA specifying three factors. In addition, three of the factors had secondary loadings suggesting that the varimax rotation, which forces all items into independent groups, may not be the optimal solution and an oblimin rotation, which allows items to correlate, may be a better solution for the data. A direct oblimin rotation is used when the variables could be correlated to each other and an oblique (non-orthogonal) solution is needed (DeVellis, 2017). The Forced Factor Analysis with a varimax and then direct oblimin rotation for construct validation was explored for the three subscales on the NEQ.

Forced factor results with both rotation solutions had the first three items of the NEQ-1 loading more strongly with the NEQ-4 than their own subscale; however the majority (5 out of 9) of the items did load together on their own cluster for NEQ-1 in both solutions. For the NEQ-4, only 5 of the 13 items grouped together (less than 50%) with the others split between the other two subscales. The NEQ-5 subscale only had one

secondary loading on the Forced Factor varimax rotation which was resolved with the oblimin rotation. Overall, the Forced Factor analysis for the NEQ-5 subscale of 5 items as created by Beadle, et al. (2011) reflected a very coherent and valid subscale. Because varimax rotations are more easily interpreted and the results between the two approaches did not substantially differ, the results of the Forced Factor analysis with varimax rotation for the NEQ instrument are presented in Table 4.5, followed by the Scree Plot for the NEQ which is presented in Figure 4.1.

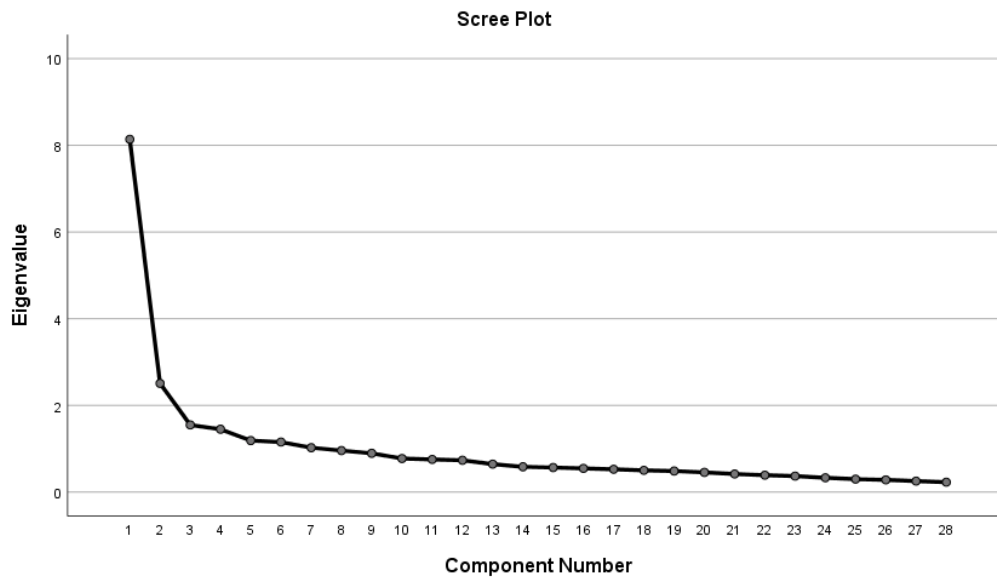
**Table 4.5: NEQ Forced Factor Analysis with Varimax Rotation**

Principal Component Analysis/Varimax with Kaiser Normalization	Component		
	1	2	3
1. Adolescent Young Adult (AYA) patients understand why they participate in cancer clinical trials	.076	.105	.678
2. AYA patients want to participate in cancer clinical trials	.141	.126	.596
3. AYA patients request to participate in cancer clinical trials	.365	.068	.419
4. AYA patients have unrealistic expectations of the treatments in cancer clinical trials*	.431	.602	.126
5. AYA patients believe that the treatments in cancer clinical trials offer a better chance of benefit than standard treatment	.623	.060	.196
6. AYA patients who participate in cancer clinical trials are more motivated to do well because they participate in a trial	.574	.039	.087
7. AYA patients do not like being asked to be in a cancer clinical trial*	.527	.263	.199
8. AYA patients will participate in anything that offers them hope	.639	.049	.212
9. AYA patients will participate in cancer clinical trials even if they know the treatments will not cure them	.559	.087	.248
10. Adolescent Young Adult (AYA) patients consent freely	.297	.260	.528
11. AYA patients have enough time to decide whether or not to participate in clinical trials	.158	.321	.586
12. AYA patients do not understand the risks of participating in cancer clinical trials*	.322	.503	.436
13. AYA Patients are willing to participate in cancer clinical trials even if the treatments have toxic effects	.407	.562	.248
14. AYA patients are unrealistic in their expectations of the benefits from cancer trial treatments*	.360	.329	.263
15. AYA patients do not fully understand the cancer clinical trials to which they consent*	.244	.437	.492
16. AYA patients give consent quickly	.622	-.008	.105
17. AYA patients participate knowingly in trials of limited drug efficacy	.628	.150	.119
18. AYA patients are willing to receive toxic treatments	.388	.377	.017
19. AYA patients are coerced to participate in cancer clinical trials*	.188	.027	.668

20. AYA patients do not realize they are participating in a cancer clinical trial*	.057	.283	.615
21. AYA patients understand how they can withdraw from a cancer clinical trial	.068	.319	.552
22. AYA patients would prefer the doctor decide about their participation in a cancer clinical trial	.587	.133	-.187
23. AYA patients understand their prognosis	-.137	.602	.284
24. AYA patients understand their treatment options	-.182	.609	.440
25. AYA patients are realistic about the benefits of cancer clinical trials	.203	.712	.171
26. AYA patients are realistic about the benefits of treatments other than those in cancer clinical trials	.363	.664	-.044
27. AYA patients do not understand how their cancer and its treatment will affect their survival*	-.005	.411	.303
28. AYA patients do not understand how their cancer and its treatment will affect their daily lives*	.048	.533	.172

\* Items were affirmatively coded for the purpose of final analyses.

**Figure 4.1 Scree Plot for NEQ after Forced Factor Analysis**



In the results of the exploratory Factor Analysis for the PNAS, the scree plot and eigenvalue agreed more closely. Although the scree plot (Figure 4.2) suggested that five factors could exist, the eigenvalue rule indicated four. An examination of the items



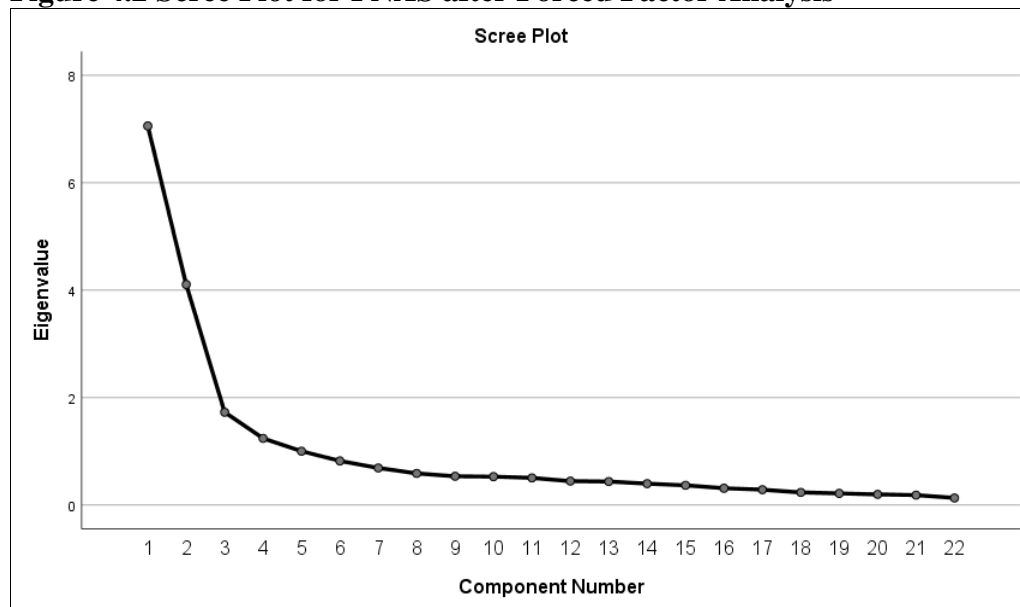
indicated the two proposed subscales were represented by two clusters of homogeneous subscale items each. This aligned with the proposed structure of the PNAS-1: Acting as Advocate subscale made up of protection, actions, and need dimensions. The PNAS-2: Work Status and Advocacy Actions subscale items all loaded almost exclusively on factor 2. As the four factor solution indicated two sub-clusters for each original subscale, the decision was made to repeat the analyses as a Forced Factor Analysis with two components with a varimax rotation. The PNAS with two components shows all item loadings with at least .40 or higher and no secondary loadings greater than .18. Factor loadings greater than .40 are generally considered to point to some degree of a relationship with another factor (Portney & Watkins, 2009). As a consequence, the PNAS scale was utilized in the final analyses without any necessary changes to its current structure as a valid tool. The results of the Factor Analysis using Principal Components Analysis (PCA) are displayed in Table 4.6, followed by the Scree Plot for the PNAS which is presented in Figure 4.2.

**Table 4.6: PNAS Forced Factor Analysis with Varimax Rotation**

Protective Nursing Advocacy Scale (PNAS)	Component	
	1	2
1. Patients need nurses to act on the their behalf	.422	.182
2. Nurses are legally required to act as patient advocates when patients are perceived to be in danger	.525	-.050
3. As a nurse, I keep my patient's best interest as the main focus of nursing advocacy	.630	-.118
4. Nurses who understand the benefits of patient advocacy are better patient advocates	.645	-.064
5. I am acting on my patient's behalf when acting as the patient's advocate	.654	-.052
6. I speak out on my patient's behalf when acting as my patient's advocate	.741	-.077
7. I am acting as my patient's voice when I am advocating for my patient	.627	.124
8. I am acting as the patient's representative when I am acting as the patient's advocate	.529	.54

9. I am advocating for my patient when I protect my patient's rights in the health care environment	.741	-.024
10. I am acting as a patient advocate when I am protecting vulnerable patients from harm	.792	-.067
11. Nurses that act on a patient's behalf are preserving the patient's dignity	.666	.099
12. I am ethically obligated to speak out for my patients when they are threatened by harm	.762	-.022
13. Nurses that provide information to patients about patient care are acting as patient advocates	.707	-.020
14. Patients have varying degrees of ability to advocate for themselves	.611	.043
15. Vulnerable patients need my protection in harmful situations	.721	-.113
16. Nurses are acting as advocates when nurses protect the rights of patients to make their own decisions	.711	-.097
17. I may suffer risks to my employment when acting as a patient advocate	-.014	.868
18. Nurses that speak out on behalf of patients may face retribution from employers	.006	.914
19. I may be punished for my actions by my employer when I inform my patients of their own rights	-.057	.896
20. Nurses that speak out on behalf of vulnerable patients may be labeled as disruptive by employers	0.12	.863
21. When nurses inform and educate patents about patient rights in the clinical setting, the nurses may place their employment at risk	-.057	.915

**Figure 4.2 Scree Plot for PNAS after Forced Factor Analysis**



In response to the solutions provided by the Factor Analyses, the decision was made to revise the three subscales for the NEQ to align the subscales accordingly. Cronbach's alpha reliability analyses were repeated on the revised NEQ subscales and the overall instrument and showed little variation from the previous Cronbach's alphas. The Cronbach's alphas for the revised NEQ subscales are presented in Table 4.7.

**Table 4.7: Cronbach's alpha for Revised NEQ and Subscales**

NEQ (Nursing Ethics Questionnaire)	Cronbach's alpha Subscales	Cronbach's Alpha Scale Overall
NEQ-1 Decision Making (9 items)	0.78	
NEQ-4 Informed Consent (13 items)	0.79	
NEQ-5 Patient Knowledge (6 items)	0.81	
NEQ Scale (1,4, &5) -Overall		0.89

The NEQ newly revised subscales, used for the analyses of the research questions of the study, are presented in Table 4.8. For the PNAS, the two subscales remained unchanged as proposed by Hanks (2008) in his doctoral research study after completion of the exploratory factor analyses.

**Table 4.8: Revised NEQ Subscales post Factor Analysis**

<b>NEQ-1 Decision-Making</b>
1. AYA patients give consent quickly
2. AYA patients participate knowingly in trials of limited drug efficacy
3. AYA patients are willing to receive toxic treatments
4. AYA patients have unrealistic expectations of the treatments in cancer clinical trials
5. AYA patients believe that the treatments in cancer clinical trials offer a better chance of benefit than standard treatment
6. AYA patients who participate in cancer clinical trials are more motivated to do well because they participate in a trial
7. AYA patients do not like being asked to be in a cancer clinical trial
8. AYA patients will participate in anything that offers them hope
9. AYA patients will participate in cancer clinical trials even if they know the treatments will not cure them
10. AYA patients would prefer the doctor decide about their participation in a cancer clinical trial

<b>NEQ-4 Informed Consent</b>
11. Adolescent Young Adult (AYA) patients consent freely
12. AYA patients have enough time to decide whether or not to participate in cancer clinical
13. AYA patients do not fully understand the cancer clinical trials to which they consent
14. AYA patients are coerced to participate in cancer clinical trials
15. AYA patients do not realize they are participating in a cancer clinical trial
16. AYA patients understand how they can withdraw from a cancer clinical trial
17. Adolescent Young Adult (AYA) patients understand why they participate in cancer clinical trials
18. AYA patients want to participate in cancer clinical trials
19. AYA patients request to participate in cancer clinical trials
<b>NEQ-5 Patient Knowledge</b>
20. AYA patients understand their prognosis
21. AYA patients understand their treatment options
22. AYA patients are realistic about the benefits of cancer clinical trials
23. AYA patients are realistic about the benefits of treatments other than those in cancer clinical trials
24. AYA patients do not understand how their cancer and its treatment will affect their survival
25. AYA patients do not understand how their cancer and its treatment will affect their daily lives
26. AYA patients do not understand the risks of participating in cancer clinical trials
27. AYA patients are willing to participate in cancer clinical trials even if the treatments have toxic effects
28. AYA patients are unrealistic in their expectations of the benefits from cancer trial treatments

## STUDY QUESTIONS

**AIM 1:** To explore pediatric oncology nurses' perceptions of ethical issues related to the process of obtaining informed consent in 16-24-year-old adolescent and young adult oncology patients who were enrolled in experimental cancer clinical trials.

**RQ 1.1:** What are the perceptions of the informed consent process in adolescent and young adult patients as perceived by pediatric oncology nurses?

In order to explore the pediatric oncology nurses' perceptions of related to the informed consent process in adolescent and young adult oncology patients enrolled in cancer clinical trials, the responses to the three NEQ subscales and the NEQ scale overall are presented in the following tables. The summary descriptive statistics are provided in Table 4.9 for each of the NEQ revised subscales and the NEQ overall. The total scores could range from 28-140 ranging from 1 = *all of the time* to 5 = *never*; 0 = *don't know*. All of the subscales and total NEQ scale had a negative or left skew. Because the overall scale has a kurtosis greater than 3, the scale has heavier tails than a normal distribution with scores on each end of the distribution. The mean score = 64.8 for the scale overall with a standard deviation of 14.5.

**Table 4.9: Summary Descriptive Statistics of NEQ subscales (n=270)**

	Mean (Standard Deviation)	Median (Interquartile Range)	Min.	Max.	Skewness	Kurtosis
<b>NEQ-1 10 items</b>	22.6 (7.0)	24.5 (9)	0	37	-1.10	1.02
<b>NEQ-4 9 items</b>	19.9 (5.5)	20(8)	0	34	-.591	.999
<b>NEQ-5 9 items</b>	22.3 (5.0)	23 (5)	0	35	-1.26	3.30
<b>NEQ Overall</b>	64.8 (14.5)	67 (16)	5	95	-1.44	3.40

Table 4.10 depicts the percentage of responses for each Likert category to each item of the revised NEQ-1: Decision-making skills (10 items). When reviewing the percentages of each answer from the responses, the only item that the participants responded *all of the time* greater than 1% of the time was to item response #8: *AYA's will participate in anything that will offer them hope* (8%). For the majority of the other item responses, the participants chose *most of the time* or *some of the time* most frequently. Sixty-seven percent of the respondents answered *most of the time* or *some of the time* for

item #10 that *AYA patients would prefer the doctor decide about their participation in a cancer clinical trial*. For the negatively worded item #7: *AYA patients do not like being asked to be in a cancer clinical trial*, 48% answered *rarely* is that the case. Overall, for this subscale, there were many respondents that answered *don't know*, as high as 29% for the item #6: *AYA patients who participate in cancer clinical trials are more motivated to do well because they participate in a trial*. In order not to affect the data analyses total scores, the *don't know* answer choice was coded as “0.” However, the *don't know* answer choice is included in Tables 4.10, 4.11, and 4.12, respectively, to present where and how often the respondents chose *don't know* when completing the instrument questionnaire.

**Table 4.10: Nurses’ Perceptions of AYA’s Decision-Making Skills - NEQ-1**

Response category (%) <i>n</i> =270	All of the time	Most of the time	Some of the time	Rarely	Never	Don't Know
1. AYA patients give consent quickly	3 (1%)	86 (32%)	128 (47%)	24 (9%)	1 (<1%)	28 (10%)
2. AYA patients participate knowingly in trials of limited drug efficacy	1 (<1%)	36 (13%)	137 (51%)	28 (10%)	1 (<1%)	67 (25%)
3. AYA patients are willing to receive toxic treatments	3 (1%)	87 (32%)	123 (46%)	30 (11%)	3 (1%)	24 (9%)
4. AYA patients have unrealistic expectations of the treatments in cancer clinical trials	3 (1%)	23 (9%)	137 (51%)	47 (17%)	2 (1%)	58 (21%)
5. AYA patients believe that the treatments in cancer clinical trials offer a better chance of a benefit than standard treatments	3 (1%)	64 (24%)	133 (49%)	11 (4%)	1 (<1%)	58 (21%)
6. AYA patients who participate in cancer clinical trials are more motivated to do well because they participate in a trial.	1 (<1%)	33 (12%)	105 (39%)	49 (18%)	4 (1%)	78 (29%)
7. AYA patients do not like being asked to be in a cancer clinical trial.	0 (0%)	4 (1%)	65 (24%)	129 (48%)	12 (5%)	60 (22%)
8. AYA patients will participate in anything that offers them hope	22 (8%)	141 (52%)	77 (29%)	2 (1%)	0 (0%)	28 (10%)
9. AYA patients will participate in cancer clinical trials even if they know the treatments will not cure them	3 (1%)	77 (29%)	141 (52%)	13 (5%)	1 (<1%)	35 (13%)
10. AYA patients would prefer the doctor decide about their participation in a cancer clinical trial	4 (1%)	57 (21%)	123 (46%)	45 (17%)	10 (4%)	31 (11%)

The pediatric oncology nurses' perception of the informed consent for the AYA's in their work environments is the subject of the NEQ-4 Informed Consent revised subscale (9 items). In this subscale, the majority of nurses answered that the AYA consented freely, generally had enough time to make their decision, understand why they participate in cancer clinical trials, they want to participate, and they understand how they could withdraw. Only three items had *all of the time* above 10 %, including item #11: *Adolescent Young Adult (AYA) patients consent freely*, item #12: *AYA patients have enough time to decide whether or not to participate*, and item # 16: *AYA patients understand how they can withdraw from a cancer clinical trial*. The response of *don't know* was chosen for every item with the highest percentage of 16% for requesting to participate in cancer clinical trials. Interestingly, for item #13: *AYA patients do not fully understand the cancer clinical trials to which they consent*, although negatively worded, there was 56% response of *some of the time* or *most of the time*. All of the responses to the NEQ-4 are presented in Table 4.11

**Table 4.11: Nurses' Perception of the Informed Consent Process - NEQ-4**

<b>Response category (%)</b> <i>n=270</i>	<b>All of the time</b>	<b>Most of the time</b>	<b>Some of the time</b>	<b>Rarely</b>	<b>Never</b>	<b>Don't Know</b>
11. Adolescent Young Adults (AYA) patients consent freely	39 (14%)	150 (56%)	64 (24%)	4 (1%)	2 (1%)	10 (4%)
12. AYA patients have enough time to decide whether or not to participate in a cancer clinical trial	32 (12%)	95 (35%)	94 (35%)	31 (11%)	1 (<1%)	17 (6%)
13. AYA patients do not fully understand the cancer clinical trials to which they consent	1 (<1%)	36 (13%)	117 (43%)	87 (32%)	9 (3%)	20 (7%)
14. AYA patients are coerced to participate in cancer clinical trials	0 (0%)	7 (3%)	40 (14%)	105 (39%)	91 (34%)	27 (10%)
15. AYA patients do not realize they are participating in a cancer clinical trial	0 (0%)	6 (2%)	59 (22%)	102 (38%)	87 (32%)	16 (6%)
16. AYA patients understand how they can withdraw from a cancer clinical trial	49 (18%)	100 (37%)	48 (18%)	39 (14%)	2 (1%)	32 (12%)

17. Adolescent Young Adult (AYA) patients understand why they participate in cancer clinical trials	16 (6%)	163 (60%)	78 (29%)	6 (2%)	0 (0%)	7 (3%)
18. AYA patients want to participate in cancer clinical trials	4 (1%)	150 (56%)	98 (36%)	1 (<1%)	0 (0%)	17 (6%)
19. AYA patients request to participate in cancer clinical trials	0 (0%)	19 (7%)	99 (37%)	98 (36%)	12 (4%)	42 (16%)

The NEQ-5 Knowledge of Clinical Trials subscale (9 items) asked the pediatric oncology nurses about their perception of the adolescent and young adult's knowledge of the clinical trial. The majority of participants responded to item # 25 that *most of the time* and *some of the time* the AYA did not know the effects that cancer and its treatment would have on their daily life (71%). For the items regarding prognosis, treatment options, and benefits of a clinical trial, the majority chose either *most of the time* or *some of the time*. In addition, to the item #24 that spoke to understanding how their cancer and treatment will affect their survival, there was a dichotomy of the majority of answers as 52% said *some of the time* and yet 32% said *rarely*. Overall, no items had *all of the time* as the response greater than 5% of the time and *don't know* also had somewhat fewer overall responses. All of the responses to the NEQ-5 are presented in Table 4.12.

**Table 4.12: Nurses' Perception of AYAs' Knowledge of Clinical Trials - NEQ-5**

Response category (%) n=270	All of the time	Most of the time	Some of the time	Rarely	Never	Don't Know
20. Patients understand their prognosis	9 (3%)	168 (62%)	86 (32%)	5 (2%)	0 (0%)	2 (1%)
21. Patients understand their treatment options	13 (5%)	164 (61%)	80 (30%)	11 (4%)	0 (0%)	2 (<1%)
22. Patients are realistic about the benefits of cancer clinical trial treatments	4 (2%)	107 (40%)	127 (47%)	18 (6%)	0 (0%)	14 (5%)
23. Patients are realistic about the benefits of treatments outside cancer clinical trials	4 (2%)	89 (33%)	135 (50%)	11 (4%)	0 (0%)	31 (11%)



24. Patients don't understand how their cancer and treatment will affect their survival	2 (<1%)	28 (10%)	141 (52%)	86 (32%)	7 (3%)	6 (3%)
25. Patients don't understand how their cancer and treatment will affect their daily lives	3 (1%)	45 (17%)	146 (54%)	67 (25%)	4 (1%)	5 (2%)
26. AYA patients do not understand the risks of participating in cancer clinical trials	0 (0%)	19 (7%)	112 (41%)	104 (39%)	13 (5%)	22 (8%)
27. AYA patients are willing to participate in cancer clinical trials even if the treatments have toxic effects	3 (2%)	87 (32%)	123 (46%)	30 (11%)	3 (1%)	24 (8%)
28. AYA patients are unrealistic in their expectations of the benefits from the cancer trial treatments	0 (0%)	24 (9%)	157 (58%)	52 (19%)	2 (1%)	35 (13%)

**AIM 1:** To explore pediatric oncology nurses' perceptions of ethical issues related to the process of obtaining informed consent in 16-24-year-old adolescent and young adult oncology patients who were enrolled in experimental cancer clinical trials.

**RQ 1.2:** Is there a relationship between the years of nursing experience and nurses' perceptions about the adequacy and understanding of the informed consent process in the 16-24 year old adolescent and young adult oncology patient?

In Table 4.13 the descriptive statistics for the newly revised NEQ are separated by years of nursing experience. From the sample population, 238 participants were categorized as an experienced nurse or one with more than five years of nursing experience. There were 32 inexperienced nurses with five or less years of experience to make up the sample of completed survey questionnaires. Overall, the mean scores for pediatric oncology nurses with greater than five years' experience were slightly lower on all three subscales in addition to the overall NEQ as compared to the inexperienced nurse ( $\leq 5$  years) reflecting greater concern with ethical issues for AYAs participating in

clinical research by the older more experienced nurse. The standard deviation, standard error, skewness, and kurtosis are also included in the table.

**Table 4.13: Summary Statistics of NEQ & Subscales by Years of Experience**

1 = ( $\leq 5$ years) 2 = ( $> 5$ years)		N	Mean	Standard Deviation	Std. Error Mean	Skewness	Kurtosis
NEQ-1	1	32	19.63	8.41	1.486	-.901	.156
	2	238	23.04	6.66	.432	-1.084	1.060
	Total	270	22.63	6.96	.424	-1.096	1.021
NEQ-4	1	32	18.81	7.56	1.337	-.845	.173
	2	238	20.03	5.18	.336	-.392	.789
	Total	270	19.88	5.51	.335	-.591	.999
NEQ-5	1	32	21.81	5.42	.958	-.973	1.164
	2	238	22.33	4.94	.320	-1.307	3.759
	Total	270	22.27	4.99	.304	-1.257	3.301
NEQ Total Score	1	32	60.25	19.09	3.38	-1.377	1.608
	2	238	65.39	13.72	.889	-1.352	3.530
	Total	270	64.78	14.512	.883	-1.439	3.396

The Pearson's correlations for the NEQ and its subscales were analyzed for years of nursing experience with years of experience both as a continuous variable and dichotomized into two ranges ( $< 5$  years vs.  $> 5$  years). Table 4.14 provides the Pearson's correlations for each of the subscales and the overall NEQ scale controlling for age, since age could influence years of nursing experience. The Pearson's correlation is used to evaluate if there is a linear relationship when there are continuous variables, such as the dichotomized nursing experience ranges (Portney & Watkins, 2009). Both will measure the extent to which two variables change together, both in strength and direction.

**Table 4.14: Pearson's Correlations for NEQ Scale**

		<b>Years in Nursing (cont.)</b>	<b>Controlled For Age</b>	<b>Years in Nursing (≤ 5yrs. vs. &gt; 5 yrs.)</b>
<b>NEQ-1</b>	Pearson Correlation	.189	-.031	.159
	Sig. (2-tailed)	.002	.616	.009
<b>NEQ-4</b>	Pearson Correlation	.085	-.029	.071
	Sig. (2-tailed)	.162	.641	.243
<b>NEQ-5</b>	Pearson Correlation	.001	-.081	.033
	Sig. (2-tailed)	.992	.184	.584
<b>NEQ Total</b>	Pearson Correlation	.123*	-.053	.115
	Sig. (2-tailed)	.043	.382	.060

While the NEQ-1 Decision-making subscale was statistically significant for years of nursing by both dichotomized years and years as a continuous variable, the fact that all the other NEQ subscales failed to strongly correlate with years of experience masked that relationship in the NEQ Total score and produced correlation coefficient close to 0, indicating no clinically meaningful relation between the years of nursing experience and the nurses' overall perceptions regarding the adequacy and understanding of the informed consent process in 16-24 year old adolescent and young adult oncology patients. Had subscale analyses not been conducted, the relationship with decision making and experience would have been missed. However, it is telling that controlling for age essentially accounted for the entire effect of experience as these two variables are highly correlated. One could argue that age is an embedded characteristic of years of experience since it is impossible to obtain one without the other and understood to be inseparable.

Figure 4.3 presents the scatter plot of years of nursing experience and NEQ scale, which visually shows that there appears to be no relationship between the two variables,

as there is no pattern of scores with multiple outliers. Although many total scores fall between 60 and 80, there are many scores that fell well below and above for this study question. Furthermore, there is indication of high variability in NEQ total score in those respondents between 0 and 20 years of nursing experience which is quite a wide range of years.

**Figure 4.3: Scatter Plot of NEQ Total Score vs. Years of Nursing Experience**



The independent samples t test was then performed to explore if there was a difference between the pediatric oncology nurses' years of nursing experience ( $\leq 5$  years vs.  $> 5$  years) and the mean score of each of the three subscales and also the NEQ total instrument score. The t test is a parametric test performed to compare the means of two groups of subjects and does not need the groups to be the same size (Portney & Watkins, 2009).

First, the Levene's test for equality of variances was used to measure the homogeneity of the data in order to determine whether an adjustment for heterogeneity

was necessary (unequal variances versus equal variances assumed). For the NEQ-1 and the NEQ-5 subscales, the Levene's test was not significant, meaning the variability in the two groups was about the same for the two subscales, and therefore the equal variances assumed t test could be performed. The NEQ-4, which encompasses the Informed Consent process, was the only subscale of the instrument that showed a significant Levene's result ( $p = .002$ ) necessitating the use of the unequal variances t-test which applies a conservative statistical adjustment factor as evidence by the reduced degrees of freedom (df). As can be seen in Table 4.15, of the subscales only NEQ-1: Decision making, demonstrated a significant value for the t test of .009 with the experienced nurses' mean = 23.04 versus the inexperienced nurses' mean = 19.63. This indicates that the inexperienced nurse perceived the decision making process in the adolescent and young adult patient as more adequate when compared to the experienced nurse.

**Table 4.15: Independent Samples T Test for NEQ by Years of Nursing Experience**

	Levene's Test For Equality of Variance		t	df	Sig. (2-tailed)	(1= <u>&lt;5</u> yrs 2 = > 5yrs) Mean for Groups	95% Confidence Interval of the Difference	
	F	Sig.					Lower	Upper
<b>NEQ-1</b>	2.74	.098	-2.63	268	.009	1 19.63 2 23.04	-5.97	-.861
<b>NEQ-4*</b>	9.78	.002	-.880	35	.385	1 18.81 2 20.03	-4.011	1.585
<b>NEQ-5</b>	.293	.589	-.55	268	.584	1 21.81 2 22.33	-2.37	1.34
<b>NEQ Total</b>	5.03	.025	-1.473	35.4	.150	1 60.25 2 65.39	-12.22	1.942

\*Unequal variances assumed for reported t-test results based on Levene's significance.

Because the adjustment for heterogeneity under the unequal variances t test is highly conservative, oftentimes legitimate relationships are missed with parametric approaches. Therefore, the scale underwent further analyses with the nonparametric Mann-Whitney U test (see Table 4.16).

Based on the Levene's results indicating the presence of heterogeneity for NEQ-4, employment of nonparametric analyses were deemed necessary to confirm findings with that scale. The nonparametric Mann-Whitney U is utilized when the data is not assumed to be normally distributed, or the Levene's test for equality of variance has shown a significant value thus rejecting the null hypothesis that there is equal variability in the two groups (Portney & Watkins, 2009). All data in nonparametric analyses are transformed into rank (ordinal) data and mean ranks calculated rather than mean scores.

The results of the Mann-Whitney U test is presented in Table 4.16. Several differences in the pattern of results emerged. First, the NEQ-1, which was only marginally significant using the parametric t-test demonstrated significance (experienced nurses' mean rank = 139.52 versus inexperienced nurses' mean rank=105.63) indicating that experienced nurses more often felt that the decision-making in the adolescent and young adult was lacking.

**Table 4.16: Mann-Whitney U Test Results for the NEQ**

	N	Mann-Whitney U test	Sig. (2-tailed)
<b>NEQ-1</b>	270	2.31	.021
<b>NEQ-4</b>	270	.294	.769
<b>NEQ-5</b>	270	.446	.655
<b>NEQ Total</b>	270	1.17	.243

Secondly, the NEQ 4, which was significant using a conservative adjustment for heterogeneity in the parametric t-test became a non-significant variable reflecting the lesser sensitivity frequently found in ordinal data. This suggests that the parametric results should be viewed with caution until additional confirmatory evidence emerges. Lastly, the significant differences found for NEQ Total scores similarly failed to be replicated which is more expected given the failure of two out of the three components to significantly differ.

Given the disparate findings between the parametric and nonparametric results, a deeper investigation was conducted by looking at the individual item responses of the NEQ instrument's three subscales. There were five item responses in which the inexperienced nurse and experienced nurse had mean scores that differed by greater than 0.4. This included four item responses from the NEQ-1 Decision-Making subscale and one item from the NEQ-4 Informed Consent subscale. The mean scores and standard deviations for the five item responses by the dichotomous inexperienced and experienced nurses' groups are displayed in Table 4.17.

Differences on the individual item responses were then analyzed using the Levene's test for equality of variances and the independent samples t test. The Levene's test showed significant heterogeneity in all five of the items (see Table 4.18), as well as, significant t test results (unequal variances assumed) for Item #1: *AYA patients consent quickly* and item #10: *AYA patients would prefer the doctor to decide about their participation in a cancer clinical trial*.

**Table 4.17: Summary of NEQ Item Responses that Differed**

NEQ Item response	Experience	N	Mean	Std. Deviation
1. AYA patients consent quickly	1*	32	1.91	1.304
	2**	238	2.52	.988
5. AYA patients believe that the treatments in cancer clinical trials offer a better chance of a benefit than standard treatments	1	32	1.72	1.397
	2	238	2.20	1.212
8. AYA patients will participate in anything that offers them hope	1	32	1.75	1.107
	2	238	2.05	.868
10. AYA patients would prefer the doctor to decide about their participation in a cancer clinical trial	1	32	1.78	1.408
	2	238	2.77	1.154
19. AYA patients request to participate in cancer clinical trials	1	32	2.44	1.664
	2	238	2.98	1.373

\*5 years' experience or less

\*\*greater than 5 years' experience

For item #1 the inexperienced nurses' mean score was 1.91 and that of the experienced nurses' was 2.52, indicating that the inexperienced nurse tended to see the item has present *most of the time* and the experienced nurse chose *some of the time*. Interestingly, for this item the inexperienced nurse thought the AYA consented quickly more often than the experienced nurse.

For item #10: the inexperienced nurses' mean score was 1.78 and the experienced nurses' mean score was 2.77. In this case, the experienced nurse was more likely to perceive that the AYA wanted their doctor involved in the decision. Although the other three items did not demonstrate significance, item #8: *AYA patients will participate in anything that offers them hope* was marginally so with a .070. The results of the Levene's test for equality of variances and the independent samples t test all five item responses are displayed in Table 4.18.

The item responses were then analyzed using the Mann Whitney U test since the significance of the Levene's test suggested that their variances were not equal for



all of the five items (#1, #5, #8, #10, and #19).

**Table 4.18: Levene's Test for Equality of Variances and Independent T test**

Item Response	Levene's Test		T test				
	F	Sig.	T*	df	Sig. (2tailed)	Mean. Diff	Std Error Diff
1. AYA patients consent quickly	6.23	.013	-2.55	35.9	.015	-.61	.24
5. AYA patients believe that the treatments in cancer clinical trials offer a better chance of a benefit than standard treatments	5.66	.018	-1.86	37.5	.070	-.48	.26
8. AYA patients will participate in anything that offers them hope	7.36	.007	-1.46	36.3	.154	-2.96	.20
10. AYA patients would prefer the doctor to decide about their participation in a cancer clinical trial	6.45	.012	-3.82	36.8	.001	-.99	.26
19. AYA patients request to participate in cancer clinical trials	6.51	.011	-1.76	36.8	.086	-.54	.31

\*Unequal variances assumed due to significant Levene's results

The results of the analysis of all five items, including the mean ranks for the inexperienced and the experienced nurse for the Mann Whitney U test, are displayed in Table 4.19. Item #1 *AYA patients consent quickly* and item #10 *AYA patients would prefer the doctor to decide about their participation in a cancer clinical trial* demonstrated significance with the Mann Whitney U. For both of these items, the experienced nurse had a larger mean rank score than the inexperienced nurse. The inexperienced nurse perceived that the AYA consented to cancer clinical trials quickly and let the doctor decide for them, more so than the experienced nurse. The other three items did not demonstrate a significant difference in their mean rank scores with the Mann Whitney U analysis.

**Table 4.19: Mann Whitney U Tests Results for the 5 NEQ items**

NEQ Item Response N=270	Mann Whitney U			1 = ≤5 yrs 2 = >5 yrs
	Test Statistic	Sig.	Df	Mean Rank
1. AYA patients consent quickly	12.16	<b>.011</b>	5	1 104.94 2 139.61
5. AYA patients believe that the treatments in cancer clinical trials offer a better chance of a benefit than standard treatments	14.49	.098	5	1 115.67 2 138.17
8. AYA patients will participate in anything that offers them hope	6.83	.211	5	1 120.72 2 137.49
10. AYA patients would prefer the doctor to decide about their participation in a cancer clinical trial	11.91	<b>.000</b>	5	1 88.72 2 141.79
19. AYA patients request to participate in cancer clinical trials	14.18	.090	4	1 114.64 2 138.30

**AIM 2:** To explore pediatric oncology nurses' perceptions about advocacy behaviors regarding 16-24 year old adolescent and young adult oncology patients who were enrolled in experimental cancer clinical trials.

**RQ 2.1:** What are the perceptions of advocacy behaviors regarding adolescent and young adult patients 16–24 years of age by pediatric oncology nurses?

The Protective Nursing Advocacy Scale (PNAS) is an instrument used to provide a quantitative measure of nursing advocacy beliefs and actions from the patient protection perspective (Hanks, 2010). Although the instrument evaluates four different domains with respect to nursing advocacy actions for the purpose of this research two subscales of

the PNAS instrument were utilized: PNAS-1: Acting as Advocate where items reflect education and experience as influential on the ability to advocate, and PNAS-2: Work Status and Advocacy Actions where items reflect the interaction between advocacy and the workplace setting (Hanks, 2010). These two PNAS subscales utilize a 5 point Likert Scale with response options of *strongly disagree*, *moderately disagree*, *neither agree nor disagree*, *moderately agree*, and *strongly agree*. The instrument is scored with *strongly disagree* =1 to *strongly agree* = 5. The highest achievable score for the scale's 21 items responses is 105, with 80 total for the PNAS-1 and 25 total for the PNAS-2.

A sample of 260 pediatric oncology nurses completed the instrument. The PNAS-1 subscale is left skewed, which then skews the entire scale to the left slightly, which results in mean scores clustered around the right side or tail of the distribution. On the other hand, the PNAS-2 subscale is skewed slightly right of the center point. The mean score for the instrument is 78.8 (sd 9.2). Table 4.20 presents the descriptive statistics for the two subscales and the overall PNAS instrument.

**Table 4.20: Summary descriptive statistics of PNAS and subscales (n=260)**

	Mean (Standard Deviation)	Median (Interquartile Range)	Min. Score	Max. Score	Skewness	Kurtosis
<b>PNAS-1 16 item</b>	68.5 (8.3)	68 (11)	16	80	-1.89	10.76
<b>PNAS-2 5 item</b>	10.3 (4.2)	10 (5.0)	5	22	.778	.046
<b>PNAS Overall</b>	78.8 (9.2)	79 (12)	26	102	-1.17	7.27

Table 4.21 depicts the numbers and percentage of responses for each Likert category to each item of the PNAS-1 Acting as an Advocate (16 items). When reviewing the percentages of each answer from the responses, the majority of participants responded as *moderately agree* or *strongly agree* to most items. The few items that had *strongly*

*disagree or moderately disagree* were the following items: #1. *Patients need nurses to act on their behalf* (14%), #7. *I am acting as my patient's voice when I am advocating for my patient* (11%), and #8. *I am acting as the patient's representative when I am acting as the patient's advocate* (21%).

There were four items that had *neither agree nor disagree* greater than 10 % of the time and these items were #1. *Patients need nurses to act on their behalf* (12%), #7. *I am acting as my patient's voice when I am advocating for my patient* (17%), and #8. *I am acting as the patient's representative when I am acting as the patient's advocate* (14%), and #11. *Nurses that act on a patient's behalf are preserving the patient's dignity* (20%). Overall, for the PNAS-1 subscale, most study participants responded favorably to the majority of the advocacy statements, which indicates that they perceive advocacy action behaviors in their role as pediatric oncology nurses with the adolescent and young adult patient undergoing cancer clinical trials in their work setting.

**Table 4.21: Acting as an Advocate – PNAS-1**

Response category (%) <i>n</i> =260	Strongly Disagree	Moderately Disagree	Neither Agree nor Disagree	Moderately Agree	Strongly Agree
1. Patients need nurses to act on their behalf	19 (7%)	17 (7%)	32 (12%)	106 (41%)	86 (33%)
2. Nurses are legally required to act as patient advocates when patients are perceived to be in danger	8 (3%)	5 (2%)	9 (3%)	102 (39%)	136 (53%)
3. As a nurse, I keep my patient's best interest as the main focus of nursing advocacy	5 (2%)	0 (0%)	6 (2%)	94 (36%)	155 (60%)
4. Nurses who understand the benefits of patient advocacy are better patient advocates	5 (2%)	3 (1%)	12 (5%)	86 (33%)	154 (59%)
5. I am acting on my patient's behalf when acting as the patient's advocate	3 (1%)	10 (3%)	16 (6%)	111 (43%)	120 (47%)
6. I speak out on my patient's behalf when acting as my patient's advocate	2 (<1%)	6 (2%)	14 (5%)	130 (50%)	108 (42%)
7. I am acting as my patient's voice when I am advocating for my patient	6 (2%)	22 (9%)	45 (17%)	103 (40%)	84 (32%)
8. I am acting as the patient's representative when I am acting as the patient's advocate	8 (3%)	48 (18%)	35 (14%)	106 (41%)	63 (24%)
9. I am advocating for my patient when I protect my patient's rights in the health care environment	4 (1%)	0 (0%)	3 (1%)	123 (48%)	130 (50%)

10. I am acting as a patient advocate when I am protecting vulnerable patients from harm	2 (<1%)	0 (0%)	5 (2%)	92 (36%)	161 (62%)
11. Nurses that act on a patient's behalf are preserving the patient's dignity	3 (1%)	8 (3%)	51 (20%)	107 (41%)	91 (35%)
12. I am ethically obligated to speak out for my patients when they are threatened by harm	2 (<1%)	0 (0%)	2 (<1%)	81 (31%)	175 (68%)
13. Nurses that provide information to patients about patient care are acting as patient advocates	2 (<1%)	9 (3%)	17 (6%)	119 (46%)	113 (44%)
14. Patients have varying degrees of ability to advocate for themselves	3 (1%)	1 (<1%)	4 (2%)	122 (47%)	130 (50%)
15. Vulnerable patients need my protection in harmful situations	2 (<1%)	1 (<1%)	23 (9%)	114 (44%)	120 (46%)
16. Nurses are acting as advocates when nurses protect the rights of patients to make their own decisions	2 (<1%)	2 (<1%)	6 (2%)	124 (48%)	126 (49%)

The PNAS-2 subscale reviewed work status and advocacy actions (5 items). The majority of respondents chose *strongly disagree* or *moderately disagree* to all of the items in the subscale alluding to the fact that the work setting does not impede their ability to advocate for patients. In addition, the *neither agree nor disagree* was chosen from 9 - 17% of the time. One item had a response percentage of 12% to *moderately agree* and that was “Nurses that speak out on behalf of patients may face retribution from employers”. For the item, “I may suffer risks to my employment when acting as a patient advocate,” there were 11% in agreement statements and another 14% of *neither agree nor disagree*. Table 4.22 presents the percentages of responses for each of the items for the 260 participants who completed the subscale.

**Table 4.22: Work Status and Advocacy Actions – PNAS-2**

Response category (%) <i>n</i> =260	Strongly Disagree	Moderately Disagree	Neither Agree nor Disagree	Moderately Agree	Strongly Agree
17. I may suffer risks to my employment when acting as a patient advocate	73 (28%)	123 (47%)	37 (14%)	23 (9%)	4 (2%)

18. Nurses that speak out on behalf of patients may face retribution from employers	70 (27%)	121 (46%)	36 (14%)	31 (12%)	2 (<1%)
19. I may be punished for my actions by my employer when I inform my patients of their own rights	103 (40%)	118 (45%)	23 (9%)	16 (6%)	0 (0%)
20. Nurses that speak out on behalf of vulnerable patients may be labeled as disruptive by employers	60 (23%)	110 (42%)	44 (17%)	40 (6%)	6 (2%)
21. When nurses inform and educate patents about patient rights in the clinical setting, the nurses may place their employment at risk	83 (32%)	127 (49%)	32 (12%)	17 (6%)	1 (<1%)

**AIM 2:** To explore pediatric oncology nurses' perceptions about advocacy behaviors regarding 16-24 year old adolescent and young adult oncology patients who were enrolled in experimental cancer clinical trials.

**RQ 2.2:** Is there a relationship between the years of nursing experience and the perceptions of nurses about their advocacy behaviors for 16-24 year old adolescent and young adult oncology patients?

In order to explore if there is a relationship between the perception of nurses about their advocacy behaviors and the pediatric oncology nurses' years of nursing experience, the summary statistics were first displayed and reviewed. There is little difference in the mean scores between the pediatric oncology nurses with less than or equal to five years of experience and the nurse with greater than five years of nursing experience. Table 4.23 presents the summary descriptive statistics for the PNAS and its subscales for the years of nursing experience ( $\leq 5$  years vs.  $> 5$  years) for the inexperienced nurse vs. the experienced nurse for the sample group.

**Table 4.23: Summary Statistics of PNAS & Subscales by Years of Experience**

1 = ( ≤ 5years) 2 = (> 5 years)		N	Mean	Standard Deviation	Std. Error Mean	Skewness	Kurtosis
<b>PNAS-1</b>	<b>1</b>	31	68.97	11.55	2.07	-3.29	14.91
	<b>2</b>	229	68.48	7.79	.52	-1.29	7.73
	<b>Total</b>	260	68.54	8.30	.52	-1.89	10.76
<b>PNAS-2</b>	<b>1</b>	31	10.32	4.04	.73	.25	-8.28
	<b>2</b>	229	10.29	4.23	.28	.84	.15
	<b>Total</b>	260	10.29	4.2	.26	.79	.05
<b>PNAS Total Score</b>	<b>1</b>	31	79.29	12.11	.26	-2.78	12.42
	<b>2</b>	229	78.77	8.76	.58	-6.37	5.02
	<b>Total</b>	260	78.83	9.19	.57	-1.17	7.27

The number of respondents for the two groups were uneven at 31 and 229, respectively. In addition, there were two PNAS-1 scores of 16, meaning that *strongly disagree* was chosen for all 16 items of the scale, which were outliers, with one respondent in each dichotomous group of years of nursing experience. The PNAS subscale had a range of scores from 5 (all *strongly disagree*) to 22, but is overall skewed slightly right of the center point. The PNAS-1 subscale is skewed to the left and has more variability in responses for the inexperienced group. The direction of the skewness is unchanged by separating the mean scores by years of nursing experience.

To evaluate years of nursing experience both as dichotomous variable (≤ 5 years vs. > 5 years), Pearson correlations were calculated the overall PNAS scale score and each of its subscales. In addition, age was included as a continuous variable since it had surfaced as a possible covariant in the preliminary analysis, although both age and years of experience would increase in a linear trajectory. The resultant coefficients of the two subscales and total PNAS were close to zero (0) and the p-values were all greater than

.05, indicating there was not enough evidence to conclude there is a relationship or correlation between either of the PNAS or its two subscales and years of nursing experience. The Pearson's correlations for the PNAS scale are displayed in Table 4.24.

**Table 4.24: Pearson's Correlations for PNAS Scale**

		Years in Nursing	Age	Years in Nursing (≤ 5yrs. vs. > 5 yrs.)
<b>PNAS-1</b>	Pearson Correlation	.039	.057	-.019
	Sig. (2-tailed)	.536	.360	.760
<b>PNAS-2</b>	Pearson Correlation	.013	.073	-.003
	Sig. (2-tailed)	.838	.242	.966
<b>PNAS Total</b>	Pearson Correlation	.041	-.018	-.018
	Sig. (2-tailed)	.515	.770	.767

The Independent samples t test was performed on the data to explore if there was a difference between the pediatric oncology nurses' dichotomized groups of years of nursing experience and the mean score of each of the two PNAS subscales and the PNAS total score. Table 4.25 displays the results of the analysis using the t test.

**Table 4.25: Independent T Test for PNAS & subscales by Years of Nursing Practice**

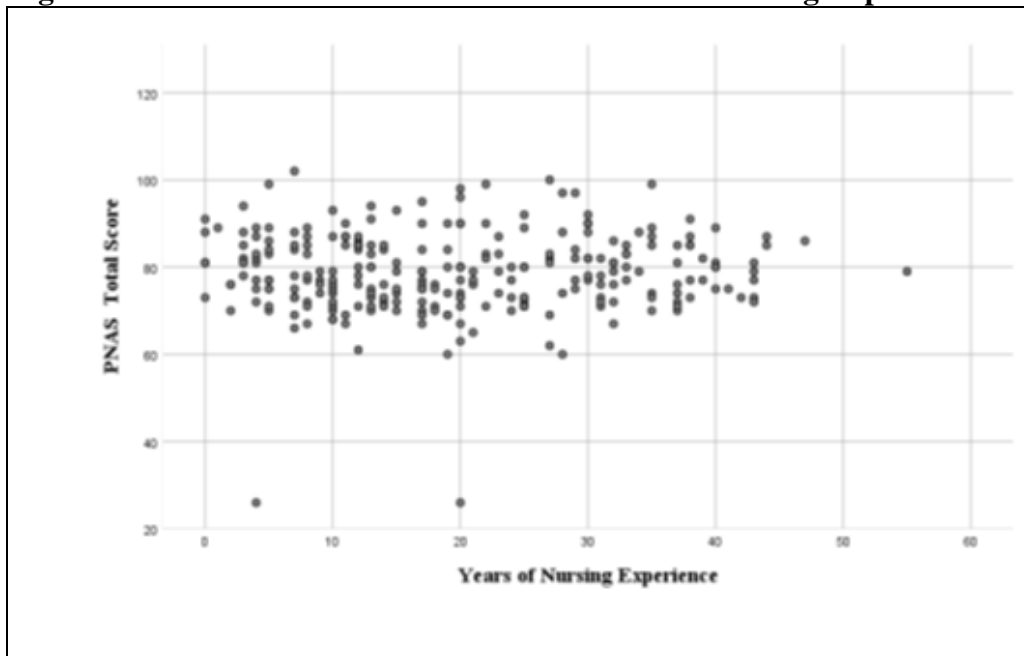
	Levene's Test For Equality of Variance		t	df	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
	F	Sig.					Lower	Upper
<b>PNAS-1</b>	.560	.455	1.51	256	.132	2.023	-.613	4.659
<b>PNAS-2</b>	.098	.754	.053	256	.957	.044	-1.572	1.659
<b>PNAS Total</b>	.885	.348	1.34	256	.181	2.067	-.971	5.104



The Levene's test showed no significance for either of the subscales or the PNAS total instrument indicating homogeneity across groups. There were no significant differences between the dichotomous groups of years of nursing experience groups on mean scores for the two subscales or the total PNAS score, as well.

Figure 4.4 is the scatter plot of years of nursing experience as a continuous variable and PNAS scale total score. It visually illustrates that there appears to be no relationship between the overall PNAS scores and the years the pediatric oncology nurses have been in nursing. The expected relationship would be that the pediatric oncology nurse would learn and utilize more advocacy behaviors as they gain experience in the advocacy situations and experience the work environment as favorable to advocacy actions, providing a slope in a linear direction from left to right.

**Figure 4.4: Scatter Plot of PNAS Scale vs. Years of Nursing Experience**



**AIM 3:** To examine if pediatric oncology nurses' protective advocacy skills and behaviors are related to perceptions of ethical issues that may arise in the process of obtaining adequate and fully understood informed consent in the care of 16-24 year old adolescent and young adult oncology patients, and whether their years of nursing experience affect this relationship.

**RQ 3.1:** Is there a relationship between the nurses' perception of advocacy behaviors (PNAS) and their perceptions about and experiences with ethical dilemmas they have encountered in obtaining informed consent (NEQ) from 16-24 year old adolescent and young adult oncology patients?

In order to test the study question about the relationship between the pediatric oncology nurses' perception of advocacy behaviors and their experiences with the ethical dilemmas that arise during the informed consent process, it was necessary to compare the PNAS scale to the NEQ scale. First, each subscale was compared to each other and then the overall scales. Pearson's correlation was used to compare each of the NEQ subscales to each of the PNAS subscales and then the total NEQ to the total PNAS scales.

In order to interpret results of the Pearson's correlations it is useful to outline the direction of meaning for each scale. Since the PNAS-1 (Acting as an Advocate) scores the scale starting with 1= *strongly disagree*, the higher the total score on the subscale, the more the participant sees the pediatric oncology nurse as an advocate for the AYA patient. On the other hand, the PNAS-2 (Work Status and Advocacy Actions), utilizes the same Likert responses, however a high score conveys that the work environment is *not* conducive to advocacy behaviors. The NEQ, also a Likert scale for responses, has 1= *all of the time*. Therefore, a lower score correlates with the items existing or necessary

“all of the time” and is the outcome achieved if the informed consent and patient knowledge of clinical trials are present, as well as, the AYA is able to utilize successful decision –making skills.

The desired relationship would be low scores on the NEQ associated with high scores on the PNAS-1 and low scores on the PNAS-2, meaning that the pediatric oncology nurse works in an environment that allows for nursing advocacy actions and perceive they can act upon ethical issues that may arise in the informed consent process with adolescent and young adult patients. Conversely, high scores on the NEQ with low scores on the PNAS-1 and high scores on the PNAS-2 demonstrate the opposite relationship where the pediatric oncology nurse does not work in an environment conducive to advocacy behaviors nor perceives that there is an adequate informed consent process. As can be seen from Table 4.26, a relationship between the two instruments cannot be established. The two scales overall scores do not demonstrate a significant relationship ( $p > .05$ ) when correlated. Although the PNAS-1 does demonstrate a slight negative relationship with the NEQ, the correlation is not significant.

**Table 4.26: Pearson’s Correlations for the NEQ and PNAS scales**

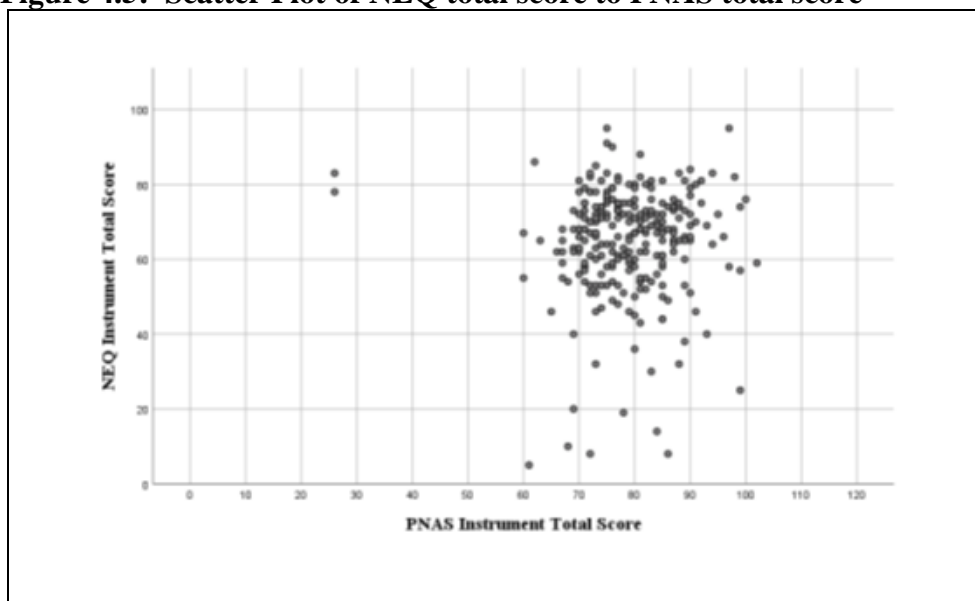
		<b>NEQ-1</b>	<b>NEQ-4</b>	<b>NEQ-5</b>	<b>NEQ Total</b>
<b>PNAS-1</b>	Pearson Correlation	-.020	-.113	-.042	-.067
	Sig. (2-tailed)	.745	.068	.500	.280
<b>PNAS-2</b>	Pearson Correlation	.030	.174**	.249**	.166**
	Sig. (2-tailed)	.633	.005	.000	.007
<b>PNAS</b>	Pearson Correlation	-.005	-.023	.076	.015
<b>Total</b>	Sig. (2-tailed)	.940	.711	.224	.809

\*\*, Correlation is significant at the 0.01 level (2-tailed).

The PNAS-2 does demonstrate a relationship with the NEQ-4 and NEQ-5 ( $p < .05$ ), but not with the NEQ-1 ( $p > .05$ ), indicating for the two Nursing Ethics Questionnaire (NEQ) subscales (4 & 5) that work status and advocacy correlates with the nurses' perception of the informed consent process and patient knowledge.

The scatter plot for the NEQ and PNAS overall instrument scores, with each compared to the other is displayed in Figure 4.5. Although there is somewhat of a majority cluster of scores evident, there are many outliers including two scores that are to the far left of the scatter plot. In addition, because the scatter plot results of the NEQ were scattered throughout, the relationship to the more linear pattern of the PNAS could not establish a relationship between the increase in the perceived knowledge of the informed consent process and the advocacy actions behaviors of the pediatric oncology nurses.

**Figure 4.5: Scatter Plot of NEQ total score to PNAS total score**



**AIM 3:** To examine if pediatric oncology nurses' protective advocacy skills and behaviors are related to perceptions of ethical issues that may arise in the process of obtaining adequate and fully understood informed consent in the care of adolescent and young adult oncology patients 16-24 years, and whether their years of nursing experience affect this relationship.

**RQ 3.2:** Do years of pediatric oncology nursing experience impact the relationship between nurses' perception of advocacy behaviors (PNAS) and their perceptions about and experiences with ethical dilemmas they have encountered in obtaining informed consent (NEQ) from 16-24 year old adolescent and young adult oncology patients?

The two instruments and their subscales were compared controlling for years of pediatric oncology nursing experience as a continuous variable to see if the length of time as a pediatric oncology nurse would impact the perceptions of nursing advocacy and ethical dilemmas in the informed consent process with the 16-24 year old adolescent and young adult oncology patient. The results of these analyses are presented in Table 4.27.

There was no demonstrated significant relationship between the two scales controlling for years of nursing oncology experience, except the correlation between the two subscales (NEQ-4 and NEQ-5) and the PNAS-2. The relationship of perceiving the work environment favorable to advocacy behaviors with years of experience would be expected, however there was not a relationship between the any of the NEQ subscales and the PNAS-1. All three subscales of the NEQ demonstrate a very slight negative correlation with the PNAS-1 and positive one with the PNAS-2, however it is not enough

of a correlation to generate a significant result.

**Table 4.27: NEQ vs. PNAS Controlling for Years of Oncology Nursing Experience**

			PNAS-1	PNAS-2	PNAS Total
<b>Years of Oncology Nursing Experience</b>	<b>NEQ-1</b>	Correlation	-.030	.037	-.010
		Significance (2-tailed)	.630	.549	.873
		Df	257	257	257
	<b>NEQ-4</b>	Correlation	-.118	.177	-.025
		Significance (2-tailed)	.059	.004	.688
		Df	257	257	257
	<b>NEQ-5</b>	Correlation	-.038	.246	.078
		Significance (2-tailed)	.543	.000	.210
		Df	257	257	257
	<b>NEQ Total</b>	Correlation	-.072	.170	.013
		Significance (2-tailed)	.249	.006	.839
		Df	257	257	257

The correlation result was negative meaning that a low score on the NEQ corresponded with a high score on the PNAS-1 and vice versa. However, the correlation was a positive result between the NEQ scale and the PNAS-2, implying that a low score on the NEQ corresponded with a low PNAS-2 score. The NEQ and PNAS total scores do not demonstrate a relationship to each other when accounting for years of nursing oncology experience. Both the NEQ and PNAS scales were then compared to each other controlling for other demographic variables of age and years of nursing experience to see if these demographic characteristics would demonstrate a relationship.

The results of the partial correlation analyses comparing the two scales while controlling for age, years of nursing experience, and years of oncology experience are presented in Table 4.28. No significant relationship was demonstrated between the NEQ

and the PNAS total scales when age, years of oncology experience, or years in nursing were controlled.

**Table 4.28: Partial Correlations of NEQ and PNAS**

Controlling Variable		Partial Correlation	
	Instrument		PNAS
Oncology Years of Experience	NEQ	Correlation	.013
		Significance (2-tailed)	.839
		Df	257
Nursing Years of Experience	NEQ	Correlation	.010
		Significance (2-tailed)	.872
		Df	257
Age	NEQ	Correlation	.014
		Significance (2-tailed)	.822
		Df	257
Age, Years of Nursing, & Years of Oncology	NEQ	Correlation	.011
		Significance (2-tailed)	.865
		Df	255

Overall, there were no demonstrated significant relationships between the PNAS and NEQ instruments and therefore, the study did not demonstrate that years of pediatric oncology nursing experience impacted the relationship between nurses' perception of advocacy behaviors and experiences with ethical dilemmas encountered in obtaining informed consent from 16-24 year old adolescent and young adult oncology patients. However, because the group of inexperienced nurses was small (n=31) relative to the experienced group (n=229), it may be that the sample size was not sufficient to demonstrate a relationship for the data set.

## **OTHER FINDINGS OF THE STUDY: NARRATIVE QUESTION**

In addition to asking the study participants to complete the NEQ and PNAS instruments, one narrative question was included in the study:

*Describe in detail, as much as you can remember, an experience of the informed consent process and/or an experience of a situation when you were called upon to be a nurse advocate involving an adolescent and young adult oncology patient participating in a cancer clinical trial.*

Although the narrative question was included as the last question of the survey, not all participants chose to answer the open-ended question section of the study. Of the 270 participants, 97 answered the narrative question either for nursing advocacy or informed consent for the adolescent and young adult patient or both. Due to the open-ended nature of the question, the participants could write as much or as little as desired, which often resulted in multiple frequency counts for a single participant on category data. The categories of narrative data used for the frequency counts were verified by an outside reviewer.

For the narrative question as to the quality of the informed consent process for the AYA patients, the most frequent responses were concerning parts of the process: allowing adequate time for decision-making and questions, understanding of risks and benefits of clinical trials, understanding the cancer clinical trial itself, the nurse being called upon to answer questions for AYA and/or the parents, understanding the toxic/side effects, and the AYA's right to say "no" at any time. Other responses were shared but not frequently voiced. The collective response categories to all of the narrative questions are



outlined in Table 4.29. Many wrote of the nurse's role in the informed consent process and how the process itself led to advocating for the AYA.

Here are several examples of the responses to the narrative question regarding informed consent:

*"The times I have been present during consenting, I would have to say 99% of the family and patient are in complete shock. They just do not want to be sick and die, so my personal belief is they would sign just about anything to achieve the goal to live. Giving the family and patient time to digest the information and formulate questions after reviewing the consent is always best... The level of education/ability to understand the information needs to be taken into consideration also. Speaking to patients and family using words they understand is paramount."* Participant #197

*"Informed consent was first discussed in nursing school and rarely discussed thereafter..."* Participant #216

*"It is not unusual for a teen to confide in their nurses how and what they are feeling--things they do not wish to tell parents for fear of upsetting them. Also the nurse can ask in a nonjudgmental manner if the teen has questions and understands what is going on now, and things to expect in the future."* Participant #197

*“In most consent situations, I review all pertinent info with the AYA patient as part of the consent process. Both the attending and I directly address the patient when getting consent as well as the parents. Child/parent dynamics can be complicated so all people in the room have a chance to speak independently. They are also given the chance to speak alone if requested.”* Participant #4

*“I have helped answer questions from teenagers who are undergoing the clinical trial consent process. These questions are usually about how treatment will affect their lives outside of the hospital.”* Participant #275

**Table 4.29: Narrative Question Responses for Informed Consent**

<i>Describe in detail, as much as you can remember, an experience of the informed consent process and/or an experience of a situation when you were called upon to be a nurse advocate involving an adolescent and young adult oncology patient participating in a cancer clinical trial.</i>	
<b>Category</b>	<b>Frequency</b>
Allowing adequate time for decision-making/questions	34
Understanding of risks/benefits of clinical trials	28
Understanding of cancer clinical trials	23
Nurse called upon to answer questions for AYA and/or parents	21
Understanding of toxic/side effects	18
AYA’s right to say “no” at any time	14
AYA looks to/wants to please parents	9
Allowing adequate time to decide	9
AYA does not give Consent/Parents supportive	7
AYA comprehends Informed Consent documents	6

AYA does not give Consent/Parents unsupportive	5
AYA and/or Parents have unrealistic expectations	5
RN left out of Informed Consent process	5
AYA wants to please provider/research team	4
Treatment given without patient assent/Prognosis withheld by parents	4
AYA gives Consent/Parents Supportive	4
Ability to comprehend/understand language	2
Diagnosis or Prognosis not known to AYA (by parents)	2
AYA assent/Parents' Consent	2

Since the narrative question also included any experiences regarding advocacy, the most frequent actions that the pediatric oncology nurses indicated they participated in were answering questions/allowing for adequate time for decision making, advocating for AYA patient when parents were involved or their decision differed from the patient, and advocating for full comprehension of the clinical trial to which they consent. In addition, nurses wrote examples of advocating for End of Life (EOL) wishes, advocating for the understanding of alternatives and the patient's beliefs, intervening in the process by utilizing other resources, such as the ethics committee or social work, and advocating for adolescent and young adult patients' voice.

Here are several examples of the participants' responses to the narrative question regarding advocacy:

*“Patient advocacy is constant and ongoing as a clinical research nurse coordinator for all patients and their families involved in the clinical trials that I manage.”* Participant # 207

*“When obtaining informed consent, I advocated by asking for clarification on specifically what our treatment goal was- as in palliative (control) vs cure. This is a very important aspect when consenting a patient, so they have realistic expectations of treatment goal. When specifying palliation (control) vs cure it can open up the conversation more for a better understanding.”* Participant #8

*“I am fortunate to work at a facility that has a culture of respecting patient rights.... I am free to voice disagreement without fear of any negative consequences.”*  
Participant #53

*“I am a strong advocate of ongoing education for all families. The treatment plan and accompanying consent should be reviewed throughout treatment. Nurses must be advocates for their patients and in my years of nursing I cannot remember an incidence when a nurse advocated for the patient with intent to do harm.”*

Participant #197

*“A cognitively delayed patient whose cancer was not responding to treatment was 19 years old. At the end of the day, bedside RN's were instrumental in being advocates*

*involving Social Work and the Ethics committed to sift through the many issues, legal and ethical.” Participant #28*

The categorical frequency of all responses by the study participants to the question of sharing a detailed time as much as you can remember when you were called upon to be a nurse advocate is summarized in Table 4.30.

**Table 4.30: Narrative Question Responses for Nurse Advocacy**

<i>Describe in detail, as much as you can remember, an experience of the informed consent process and/or an experience of a situation when you were called upon to be a nurse advocate involving an adolescent and young adult oncology patient participating in a cancer clinical trial.</i>	
<b>Category</b>	<b>Frequency</b>
Advocating for full comprehension of the clinical trial to which they consent	25
Advocating for understanding of benefits/side effects	24
Advocating for End of Life (EOL) wishes	17
Advocating for AYA patient when parents involved or their decision differs	14
Advocating for understanding of alternatives/beliefs	13
Intervening in process by utilizing other resources (ethics, social work)	11
Advocate for AYA patients' voice	11
Advocating for treatment withdrawal or refusal of participation in clinical trial.	9
Advocating that AYA and/or family is overwhelmed	7
Advocating for AYA patient with physician or clinical trial team	6
Advocating when AYA sees last “hope”	5

Nurses able to voice opinion without fear	4
Physician/PI pushing clinical trial on AYA	3
Advocating for home vs hospital therapy	2
Advocating with AYA's insurance coverage	1

## CHAPTER SUMMARY

In summary, the demographic profile of these 270 pediatric oncology nurse participants reflected some notable differences among this group from nurses in other clinical specialties as noted in a national DHHS nurse survey (2019) -This oncology group not only had more years of clinical experience but a greater number (90%) held advanced degrees than the national average of non-oncology nurses. The majority of nurses in the study indicated that they were affiliated with a teaching hospital, and importantly, a large majority provided direct care to their adolescent and young adult cancer patients.

Although these participants' reflected lengthy and in-depth experience in oncology nursing, this study was not able to establish a relationship between the years of nursing or oncology experience for the pediatric oncology nurse participants in the study, and the quality of the informed consent process, except with a select few item responses on the NEQ questionnaire. The overall favorable responses for the PNAS-1 reflected that pediatric oncology nurses felt strongly that they advocated for their adolescent and young adult patients, but did not demonstrate that the behaviors were affected by years of experience. The PNAS-2, which examined work status and advocacy action behaviors,

also did not demonstrate a statistically significant difference in mean scores with years of nursing experience. The NEQ subscales were revised after exploratory factor analysis provided indications of the 3 concepts of the subscales but in different order. The newly revised NEQ was used in the final analysis. The PNAS scale was utilized as developed by Hanks (2008). Comparisons of demographic data and total NEQ and PNAS scores did not indicate significant differences between groups of participants for the demographic data, including the years of experience.

Optional narrative responses were written by 97 of the participants with a wide variety of categories for both informed consent and nursing advocacy actions when caring for the 16-24 year old adolescent and young adult oncology patient. The relationship of the NEQ and PNAS findings to the theoretical framework, along with implications for nursing, is discussed in Chapter 5.

## **CHAPTER 5: DISCUSSION AND RECOMMENDATIONS**

### **INTRODUCTION**

This Chapter provides a brief overview of the study's purpose and rationale, a discussion of the major findings of the study and a synthesis of findings relative to the theoretical framework and relevant research noted in the review of literature. It also addresses important implications of key study results for oncology nurses related to informed consent and patient advocacy with adolescent and young adult patients. The chapter concludes with a discussion of the strengths of the study and potential limitations as well as recommendations for future research that can further examine nurses' critical advocacy roles and actions related to the informed consent process with this unique, often vulnerable population of adolescents and young adults.

The purpose of this exploratory research study was to examine nurses' perceptions of ethical issues that may arise in the process of obtaining informed consent in adolescent and young adult oncology patients enrolled in experimental clinical trials, and secondly, to examine the extent to which nurses engage in protective advocacy behaviors and actions on behalf of those patients. The relevance and significance of this study is underscored by the large and growing number of both older adolescent and young adult patients who are increasingly being diagnosed with specific forms of cancer including leukemias, lymphomas, and brain tumors and enrolled in clinical trials (Siegel et.al, 2018). Although the overall survival rate of this age group has increased, studies suggest that they often do not respond as well as adults to conventional or experimental treatments and often have to extend treatments beyond a five year period due to relapse



or related illnesses (Keegan, et.al, 2016). This group of older adolescents and young adult patients are increasingly being required to assume responsibility for their own informed consent to treatment in place of their parents who have traditionally been responsible for consent. However, there has been very limited related research which examines actual or potential ethical issues regarding the quality of the informed consent process for this age group, and importantly, their level of comprehension of proposed treatments and the overall consent process.

Pediatric oncology nurses who provide direct care for this age group in the U.S are in a unique position to serve as their advocates as they navigate the informed consent process and enter into treatment and clinical trials. Although physician researchers and scientists have legal responsibility based on federal and state regulations for obtaining informed consent from these young patients before they can be enrolled in a clinical trial, oncology nurses are a vital link between researchers and their patients. In spite of their significant caregiver roles with this age group of patients, however, there has been a striking lack of research which has addressed pediatric oncology nurses' perceptions about ethical issues in the informed consent process and their actions to help advocate for their adolescent and young adult oncology patients. This current study addressed those substantial gaps in research.

## **DEMOGRAPHIC CHARACTERISTICS**

The sample for this study consisted of 270 oncology nurses drawn from a national population in the U.S. who currently provide care to adolescent and young adult patients with cancer. The overall demographic profile of this sample provided an informative

snapshot of the participants and also reflected several notable differences between this group and those from a recent national nurse survey conducted by DHHS (2019). Nurse participants were largely White/Caucasian (86%) and female (98 %), and a mean age of 44.7 years (sd=11.58). The majority of nurses (94%) had at least a bachelor's degree, and of interest is that 39% had a Master's degree in Nursing, with 8% a Doctorate. The years of oncology nursing experience ranged from 1 to 45 years, with a mean of 15.6 years (sd=10.20). In addition, they reported that their clinical work setting was largely in a teaching hospital (61.5%) and most nurses were involved in patient care (72.9%).

In comparison, statistics for nursing demographics from the 2018 National Sample Survey of Registered Nurses reflect that the White/Caucasian nursing population was 73.3% with 26.7% self-identified as minorities. The percentage of females in the profession was listed as 90.4% (9.6 % were male) and 68.8% of nurses had a Bachelor's degree or higher, 19.3% with a Master's degree, 1.9% a doctorate (US DHHS, 2019). The average reported age for a nurse in the national study was 47.9 years.

. This level of advanced education reflected in the study group may contribute to nurses' greater knowledge and confidence in clinical skills and decision-making and may influence them to go to greater lengths to advocate for their patients.

Another important distinction from the National Nurses' Survey data is that the current study group was largely a much more experienced work force. The mean number of years of oncology nursing experience for the group was 16.4 years and years of nursing experience was 19.92. That level of experience as a nurse clinician, specifically in oncology, could promote greater feelings of nurse efficacy and willingness to serve as

advocates for adolescent and young adult patients, as well as, more opportunities to participate in informed consent deliberations.

In addition to participants being a more experienced group of nurses, the majority of pediatric oncology nurses (61%) worked in a teaching hospital and 28% worked in an outpatient clinic, and importantly, 73% of the nurses provided direct patient care. It is noteworthy that study participants reported that 97% of their adolescent and young adult patients participated in cancer clinical trials in their specific work setting. Importantly, this indicates that this group of respondents was familiar with the informed consent process for adolescent and young adult oncology patients entering clinical trials, as well as awareness of possible ethical and other issues that may arise in the process.

## **DISCUSSION OF MAJOR FINDINGS**

The purpose of this study was to explore pediatric oncology nurses' perceptions of ethical issues that may arise in the process of securing informed consent in adolescent and young adult oncology patients enrolled in experimental cancer clinical trials and to examine the extent to which the nurses engaged in protective advocacy behaviors related to informed consent. In addition, the study examined whether years of nursing experience impacted the nurses' perceptions about the ethical adequacy of the informed consent process and the presence of nursing advocacy behaviors.

AIM 1. The first Aim was to explore pediatric oncology nurses' perceptions of ethical issues related to the process of obtaining informed consent in 16-24 year old adolescent and young adult oncology patients who were enrolled in experimental cancer

clinical trials. Nurses were queried about their perceptions of ethical issues that arose during the informed consent process and the extent of adolescents and young adult oncology patients' understanding and comprehension of cancer clinical trials utilizing the Nursing Ethics Questionnaire (NEQ). Previous pediatric researchers who have studied patients' and/or their parents' knowledge of the research process and specific protocols found that many research participants of any age were misinformed about research and had incomplete comprehension of information (Poston, 2016; Flory & Emmanuel, 2004; Corbie-Smith, et al., 2002; Freimuth et al., 2001; Joffe, et al., 2001)

Although this study explored pediatric oncology nurses' perceptions of possible ethical issues related to informed consent rather than directly querying their adolescent and young adult patients, the results related to question one regarding the decision making skills (see Table 4.15) paralleled several of the previous findings of other researchers (Unguru, 2010; Hickey 2007; Ruccione, 1991). The total mean score for the NEQ (Nursing Ethics Questionnaire) was 64.8, reflecting that *most* pediatric oncology nurses who responded perceived that the informed consent process was *not adequate* all of the time, as perceptions of thorough consent would have equated to an NEQ score near or at 28. According to the instrument, lower mean scores on the NEQ scale demonstrate perceptions of higher adequacy and comprehension of the overall process of informed consent for cancer clinical trials. In addition, there was a 5 point difference in the mean scores for the NEQ total scale score between the experienced nurse (Total NEQ mean= 65.39) and the inexperienced nurse (Total NEQ mean= 60.25) indicating that the *more experienced nurses* reported perceptions of *greater inadequacy* in the informed consent

process for the adolescent and young adult patient. As previously noted, the majority of NEQ subscales failed to correlate with years of nursing experience which resulted in a similar failure when using the NEQ total score.

However, it's important to note that of the NEQ subscales, the NEQ-1 Decision-making subscale did demonstrate a significant positive Pearson's Correlation ( $r=.189$ ,  $p=.009$ ), indicating that greater years of experience is related to *more negative perceptions of adequacy* in the informed consent process for the study participants (Table 4.14). In addition to revealing the added depth of insight displayed by more experienced nurses, this finding dramatically illustrates the necessity of using subscales that parse a phenomenon into succinct domains rather than global total scores that may mask important distinctions.

Additionally, two individual item responses on the NEQ instrument did demonstrate significance ( $p < .05$ ; see Table 4.18). These items included nurses' views/perceptions about the extent to which: 1). *Adolescent & Young Adult (AYA) patients consent quickly*, and 2). *AYA patients would prefer the doctor to decide about their participation in a cancer clinical trial*. In these items, the inexperienced nurse felt the AYA contributed to the process at least *most of the time* on average, yet importantly, the experienced nurses gravitated toward the belief that this group of adolescent and young adult patients were involved in the informed consent process only *some of the time*. This significant association between the increased number of years that the pediatric oncology nurse has been practicing, and how knowledgeable they perceive the adolescent and young adult patient to be regarding the informed consent process, indicates that the more experienced the nurse, the more cautious they are about whether

they believed the adolescent and young adult had both an adequate understanding and knowledge of the process *all* of the time.

Another substantive finding for AIM 1 was that the pediatric oncology nurses in the sample frequently indicated that these patients “*wanted the doctor to decide*”, which had not been previously reported in the literature. In addition, pediatric nurse participants selected the item response option of *don’t know* to several items reflecting components of the informed consent process. For example, as many as 29% of participants chose *don’t know* for items of the NEQ-1 subscale related to the AYA’s overall decision-making skills, alluding to the belief that they could not assess if the decision making skills were present. This response demonstrated ambiguity in the nurses’ overall assessment of the AYA’s capability and comprehension of the informed consent process.

Since pediatric oncology nurses are responsible for the overall care of the adolescent and young adult and have continuing close interactions with them and their families over time, they are in a unique position to provide information regarding the informed consent process and to gauge the AYA’s response. In addition, since the findings indicate that these pediatric oncology nurses rarely selected the option that their patients fully participated in the process and fully understood key information *all of the time* but instead selected the options *most of the time* or *some of the time*, reflects that there is a pressing need to improve the quality and comprehension of informed consent for the adolescent and young adult.

Aim 2. The second Aim addressed pediatric oncology nurses’ advocacy behaviors and utilized a tool (Protective Nursing Advocacy Scale-PNAS) developed by Hanks (2008) to measure nursing advocacy beliefs and actions from the perspective of patient

protection. Based on analysis of data drawn from participants' responses to this instrument, there was little difference in the mean scores on the PNAS subscales, and that difference persisted when the years of nursing experience were compared. However, there was more variability in the PNAS-1 scores for the inexperienced group. This may reflect lesser confidence for the inexperienced nurse regarding their role in advocacy. This is not a surprising result since it seems intuitive that nurses would learn more about advocacy and engage in more advocacy-related actions as they gain experience in their role.

The study results from these participants' responses to the advocacy scale did support previous researchers' findings of nurses' advocacy behaviors in *speaking out, acting on behalf of patients, and preserving the patient's dignity* (Bu & Jezewski, 2007; Choi, 2015; Hanks, 2008; Chafey et al., 1998) and *acting as the patient's voice* (Davoodvand, et al., 2016; Haylock, 2015; Kalaitzidis & Jewel, 2015; Hank, 2010; Foley, et al., 2000).

Aim 2 also examined the possible association between nursing advocacy behaviors and years of nursing experience; however no significant differences were demonstrated in the overall scores for nursing advocacy behaviors related to the nurse participants' years of experience. This study found no significant differences between the perceptions of nursing advocacy behaviors and the experience levels of the nurses surveyed which is similar to Thacker's (2008) findings but differed from Abbaszadeh, et al.'s (2013) findings of significant differences in nurse advocacy based on experience.

Aim 3. The third Aim of the research study explored informed consent and nursing advocacy behaviors and how, if any, the years of experience impacted the

responses. There was a *demonstrated association* between the NEQ-4 Informed Consent and NEQ-5 Patient Knowledge subscales and the PNAS-2 Work status and Advocacy Actions. Overall, nurses who felt that their work environment was conducive to advocacy actions recognized their role in securing informed consent and improving patient knowledge. This was shown for both the inexperienced and experienced nurses. No association was demonstrated between the PNAS-1 Acting as an Advocate and any of the three NEQ subscales. The years of nursing experience did not demonstrate a correlation, and neither did the nurses' age or years in oncology. While the absence of evidence (i.e., failure to reject the null hypothesis of no effect) is not evidence of absence, failure to find relationships between the PNAS and NEQ dimension suggest that there is still much work to do to ensure that adolescent and young adult patients have the knowledge, decision-making, and understanding of the informed consent process to participate fully in the process, as well as, to equip the pediatric oncology nurse with the skills necessary to have conversations with this vulnerable age group.

Data from the narrative section of the study provided candid, insightful and often poignant statements and reflections about the nurse participants' experiences and perceptions about informed consent with adolescents and young adult patients with cancer. It is notable that ninety-seven of the nurse participants took the time to share individual experiences and responses to and actions taken when ethical and /or other issues arose. They were asked to share an experience about the informed consent process and/or an experience of a circumstance in which they were called upon to be an advocate on behalf of an adolescent or young adult oncology patient participating in a cancer clinical trial.



Based on their experiences related to the informed consent process, the nurse participants' narratives reflected several themes that they believed were critically important in facilitating the AYA patients' understanding of the process. These included allowing adequate time for decision-making and questions, helping them understand the potential risks and benefits of clinical trials, as well as, potential toxic side effects of treatment, their ethical and legal right to say "no" or refuse experimental treatments at any time, and the importance of family involvement in the process when feasible. These narrative responses expanded on the survey questions by adding unique dimensions of the informed consent process with adolescents and young adults.

One of the most important findings that emerged from the narratives was the extent to which these pediatric oncology nurses reported that they had engaged in various forms of advocacy on behalf of their adolescent and young adult patients. For example, they took extra measures to ensure that their patients fully comprehended the nature and rigor of clinical trials, as well as, had a better understanding of the possible benefits and potential harsh side effects. Many also noted that they had engaged their patients who were terminally ill in important discussions about their beliefs and preferences regarding end of life (EOL) and possible withdrawal of life-supportive treatments. They also noted their discussions with older adolescent and young adult patients regarding some of the difficult issues that arise when parents want to be more involved in decision-making or when their decision differ from the adolescent and young adult.

These narrative findings of very active nursing advocacy reinforce the research findings of Gerber (2018), Selander, et al., (2012), Grace (2001) and others that advocacy is a fundamental and crucial part of ethical nursing practice. These narrative responses, in

conjunction with the Advocacy survey responses, underscore that there are often inherent ethical issues in the informed consent process with the adolescent and young adult and in response, pediatric oncology nurses' often engage in on-going advocacy actions and behaviors. Pediatric oncology nurses are in a unique position to make a positive impact on the informed consent process for adolescent and young adult.

## **SUMMARY OF FINDINGS**

The demographic profile of study participants revealed that they were a very experienced workforce with a majority having advanced educational degrees and that a majority worked in a teaching hospital. Importantly these nurses reported that ninety seven percent of their patients were enrolled in ongoing clinical trials which reinforces the need for nurses to be actively engaged in the informed consent process. The majority of this sample was female and White /Caucasian, so the perspectives and experiences of male and ethnically diverse participants could not be adequately examined.

Although the demographic variables of education, age, role, setting, and certification did not have an anticipated impact on the study's results, there were significant findings that are directly related to study questions. For example, *years of experience* did emerge as a differentiator when addressing nurses' confidence in the adequacy of a patient's comprehension and understanding of the informed consent process. The fact that experience gave nurses needed insight and confidence to act as advocates for young patients highlights opportunities for utilizing other mechanisms (e.g., education, research opportunities, mentoring) to bolster greater efficacy in nursing

staff. The Nursing Ethics Questionnaire (NEQ) had two individual item responses that demonstrated *significance in the adequacy of informed consent between the experienced and inexperienced nurse*. Lastly, the high number of qualitative responses from nurses who answered the optional narrative question provided a range of anecdotal experiences, comments and thoughts on informed consent and nursing advocacy in the adolescent and young adult population speaks strongly to the need to utilize feedback mechanisms that might not have been captured with the format of a survey questionnaire alone.

#### **THEORETICAL FRAMEWORK RELATIONSHIP**

Gadow's pivotal concept of existential advocacy was the guiding theory for this research study since pediatric oncology nurses can often play a critical advocacy role in assisting adolescent and young adult patients determine and clarify their beliefs, values, and goals with the available treatment options (Gadow, 1989). Although adolescents are not yet adults, their ability to make decisions about their course of treatment and medical care has been shown to be accepted by professionals in pediatrics and in child development. Older adolescents and young adults are recognized as adept with self-determination, especially in the presence of life-threatening illness (Caplan, 2007, Frankel, et al., 2005). The results of the study underscore that pediatric oncology nurses often see themselves as advocates for the adolescent and young adult population and clearly recognize many of the actual or potential ethical issues that are inherent in informed consent as many parts of the process are not seen as completed all of the time. Responses by pediatric oncology nurses to the NEQ and PNAS instruments, which

explored the adolescent and young adult's self-determination and ability to make their own decisions, supported Gadow's (1980) ideal nurse–patient relationship that encourages the adolescent and young adult to decide for themselves about all personal matters, which includes healthcare decisions.

## **STRENGTHS**

One of the major strengths of this research is that it was one of the first studies in the U.S. to examine nurses' perceptions about the adequacy of and ethical issues that may arise in the informed consent process with adolescent and young adult oncology patients. In addition, the study explored an important related question - was there a possible relationship between nurses' perceptions about the quality and ethical nature of the informed consent process and their decisions to engage in advocacy on behalf of their patients. There has been a striking overall lack of research within the nursing profession about specific actions that nurses have taken or may take to protect their patients when they believe there are possible ethical violations. In addition, although adolescent and young adult patients are a growing segment of the population recruited into cancer clinical trials, there has been limited research about the nature of their knowledge about and/or participation in the informed consent process. Furthermore, survey questionnaires were fully completed and returned by pediatric oncology nurses in 44 states which provides a nationwide representation. Importantly, ninety-seven pediatric oncology nurses responded to the optional opportunity to share a narrative describing an experience related to informed consent issues with adolescents or young adults, demonstrating that many nurses are compelled to share their experiences when invited to do so.

## STUDY LIMITATIONS

There were a number of limitations in the current study including the use of a non-randomized convenience sample of 270 pediatric oncology nurses recruited from across the U.S. which may limit the generalizability of the results to a larger population of oncology nurses. The limited sample size and the relatively small number of inexperienced nurses may have affected the ability to find a relationship between the experienced and inexperienced nurse in both the adequacy of informed consent and nursing advocacy behaviors. Furthermore, the online survey format, although seemingly easier to reach a large audience of pediatric oncology nurses across the United States, was negatively impacted by email security and firewalls. It is also possible that the nurses did not open the email survey because they did not recognize the sender, or the email server sent the email inquiry to the junk or spam folder.

The demographic characteristics of the sample related to gender, ethnicity, and education affected its generalizability to the larger population of nurses. In addition, the Nursing Ethics Questionnaire's (NEQ) item selection choice of *don't know* and the *neither disagree nor agree* of the Protective Nursing Advocacy Scale (PNAS) may have encouraged the participants to choose a neutral response. Lastly, the self-participation survey may have only captured pediatric oncology nurse participants who had a specific interest in the topic of informed consent in the adolescent and young adult patient.

## IMPLICATIONS FOR NURSING

One of the major implications of this study's findings is a need for oncology

nurses to develop a greater awareness of the overall complexity and impact of the informed consent process for adolescent and young adult oncology patients. This process is often challenging and complicated by the relative maturity of adolescents and young adults to make critical informed medical decisions on their own behalf, as well as, potentially powerful family dynamics among parents who may believe they should retain their longstanding decision authority. The adolescents/young adults' informed consent can also be greatly affected by their often dynamic and evolving health care status as they progress through various stages of cancer and treatments.

Although the study found only a marginal difference in inexperienced and experienced nurses' informed consent, results suggested that novice nurses working with adolescent and young adults often overestimated adolescents' knowledge about and actual involvement in the informed consent process. Those nurses may need more education and guidance about the process. One of the striking implications for nursing was the finding that nurses who believed their work environment was conducive to advocacy actions recognized their unique role in facilitating informed consent and in improving their patients' knowledge of and participation in the process.

The anecdotal experiences cited in the narrative responses highlighted nurses increased awareness of the importance of family and peer dynamics, interdisciplinary teams' collaboration, and support for nursing advocacy behaviors when working with the adolescent and young adult oncology patient. Lastly, nurses can potentially affect policy decisions in their practice regarding the process that is used to obtain informed consent with this group of AYA's, as well as, help improve the quality of information about clinical trials and evaluation of patients' understanding of that information. Nurses'

strategic engagement in the informed consent process, including advocacy actions on behalf of their patients when needed, can potentially improve the safety and quality of patient care for this age group and may have broader effects on the informed consent process used with other groups of patients.

## **RECOMMENDATIONS FOR FUTURE RESEARCH**

Based on the findings of this current exploratory study, there is a need to replicate this study among a larger, more representative sample of pediatric oncology nurses that include nurses who are more ethnically diverse and also have a broader range of years of oncology nursing experience with adolescent and young adult cancer patients. Expanding the diversity and experience levels of the nurse sample may provide more substantial data about the differential impact of those variables on nurses' perceptions about the adequacy of the informed consent process with their adolescent and young adult patients and their decisions to engage in advocacy on their behalf.

There is also a need for parallel research that examines the informed consent process from the perspective of the adolescent and young adult patients themselves, as well as, potential ethical issues that may arise with this unique population. Adolescent and young adult patients remain a vulnerable population and both quantitative and qualitative studies could provide valuable information regarding their perspectives and experiences with the informed consent process. In addition, there is a need for future studies that further examine the extent and nature of nursing advocacy behaviors among pediatric oncology nurses and other nurse specialty groups.

## CONCLUSIONS

The results of this exploratory study provided further support for the current body of related research literature that suggests the informed consent process that is currently used with adolescent and young adult oncology patients who are recruited into clinical trials is often very inadequate. The results of this study reflect that oncology nurse participants recognized that adolescent and young adults may not fully understand the impact of their decisions, the complex nature of cancer clinical trials, or how it will impact their survival and daily lives. Based on that knowledge, this group of nurses reported that they often take advocacy actions to try to improve their patients' understanding and protect their health and safety.

Finally, the results point to a critical need for ongoing research related to the ethical and potential legal issues in the informed consent process with this vulnerable group of adolescent and young adult patients, as well as additional research which addresses differential knowledge and advocacy responses of both inexperienced and experienced oncology nurses as well as those from differing ethnic and cultural backgrounds. There is also a pressing need for seminal research which examines the perspectives and experiences of adolescent and young adult oncology patients relative to informed consent and their involvement in decision-making about entering experimental cancer clinical trials.



## APPENDIX A: DEMOGRAPHIC DATA INFORMATION SHEET

<b>Demographic Information:</b> The following questions ask about your work in oncology and background information about yourself. Unless otherwise indicated, please <b>circle ONE response</b> only.	
Are you: 1. Male 2. Female	How many years have you been in Nursing? _____ What is your age? _____
Ethnicity: 1. Caucasian 2. African American 3. Hispanic 4. Asian 5. Other	What is the highest qualification you have obtained? 1. Associate degree 2. Bachelor degree 3. Master degree 4. Doctorate 5. Other (Please Specify)
U.S. state in which you are employed: _____	Which Nursing Certification do you currently have? 1. ONC 2. APHON 3. Other (Please specify)
Do adolescent and young adult patients (AYA) participate in cancer clinical trials in your work setting? Yes_____ No_____ N/A_____	What percentage of AYA patients in your work setting do you estimate are participating in cancer clinical trials: 1. 0% 2. 1-25% 3. 26- 50% 4. > 50% 5. Not applicable (not involved in clinical care)
In what type of setting do you work? 1. Hospital - Teaching 2. Hospital – Non-teaching 3. Other - clinical setting (please state) _____ 4. Other - non-clinical setting (please state) _____	In what field of nursing do you work (if you work in more than one area, please circle the PRIMARY field in which you work)? 1. Patient care 2. Education 3. Administration 4. Clinical Research 5. Other (please specify) _____
What percentage of your work time is devoted to adolescent and young adult (AYA) oncology patients (please circle one box only) 1. 0% 2. 1-25% 3. 26-50% 4. >50% 5. Full time	How many years have you been working in oncology? _____

## APPENDIX B: NURSING ETHICS QUESTIONNAIRE (NEQ)

This survey asks a series of questions about your opinions and experiences as a nurse regarding cancer clinical trials. While you may not be involved directly in the care of adolescent and young adult patients participating in clinical trials, your views and perceptions about these issues are important.

**1 = All of the time**  
**2 = Most of the time**

**3 = Some of the time**  
**4 = Rarely**

**5 = Never**  
**6 = Don't know**

**About adolescent and young adult patients who decide to participate in cancer clinical trials:** How well do the following statements reflect **your perception** as a nurse of adolescent and young adult patients' decisions to participate in cancer clinical trials? For each item please circle the **one** response which best indicates your view.

- ☐ 1. Patients understand why they participate in cancer clinical trials
- ☐ 2. Patients want to participate in cancer clinical trials
- ☐ 3. Patients request to participate in cancer clinical trials
- ☐ 4. Patients have unrealistic expectations of treatments on cancer clinical trials
- ☐ 5. Patients believe cancer clinical trial treatments offer a better chance of benefit
- ☐ 6. Patients who participate in cancer clinical trials are more motivated to do well
- ☐ 7. Patients don't like being asked to be in cancer clinical trials
- ☐ 8. Patients will participate in anything that offers hope
- ☐ 9. Patients will participate in cancer clinical trials even if they know the treatments will not cure them

**About assessment of informed consent:** How well do the following statements reflect **your perception** as a nurse of the consent process in cancer clinical trials? For each item please circle the **one** response which best indicates your view.

- ☐ 1. Patients consent freely
- ☐ 2. Patients have enough time to decide whether to participate in cancer clinical
- ☐ 3. Patients don't understand the risks of participating in cancer clinical trials
- ☐ 4. Patients are willing to participate in cancer trials of toxic treatments
- ☐ 5. Patients are unrealistic in expecting benefits from cancer trial treatments
- ☐ 6. Patients don't understand the cancer clinical trials to which they consent
- ☐ 7. Patients give consent quickly
- ☐ 8. Patients participate knowingly in trials of limited drug efficacy
- ☐ 9. Patients are willing to have toxic treatments
- ☐ 10. Patients are coerced to participate in cancer clinical trials
- ☐ 11. Patients do not realize they are participating in a cancer clinical trial
- ☐ 12. Patients understand how they can withdraw from a cancer clinical trial
- ☐ 13. Patients would prefer the doctor to decide about their participation in a cancer clinical trial

**About patients' knowledge of their cancer:** How well do the following statements reflect **your perceptions as a nurse** of patients' knowledge of their cancer? For each item please circle **one** response which best indicates your view.

- ☐ 1. Patients understand their prognosis
- ☐ 2. Patients understand their treatment options
- ☐ 3. Patients are realistic about the benefits of cancer clinical trial treatments
- ☐ 4. Patients are realistic about the benefits of treatments outside cancer clinical trials
- ☐ 5. Patients don't understand how their cancer and treatment will affect their survival
- ☐ 6. Patients don't understand how their cancer and treatment will affect their daily lives

## APPENDIX C: PROTECTIVE NURSING ADVOCACY SCALE (PNAS)

**Instructions:** Please complete the questionnaire by placing a √ in the box to the right of each statement which most closely indicates your rating (strongly disagree, moderately disagree, moderately agree, and strongly agree) in regards to the adolescent and young adult oncology patient.

1 = strongly disagree  
2 = disagree

3 = neither agree nor disagree  
4 = agree

5 = strongly agree

- ☐ 1. AYA patients need nurses to act on their behalf
- ☐ 2. Nurses are legally required to act as patient advocates when patients are perceived to be in danger
- ☐ 3. As a nurse, I keep my AYA patient's best interest as the main focus.
- ☐ 4. Nurses who understand the benefits of patient advocacy are better patient advocates
- ☐ 5. I am acting on the AYA patient's behalf when acting as the patient's advocate
- ☐ 6. I speak out on my AYA patient's behalf when acting as my patient's advocate
- ☐ 7. I am acting as my patient's voice when I am advocating for my patient
- ☐ 8. I am acting as the patient's representative when I am acting as the patient's advocate
- ☐ 9. I am advocating for the AYA patient when I protect my patient's rights in the health care environment
- ☐ 10. I am acting as a patient advocate when I am protecting vulnerable patients from harm
- ☐ 11. Nurses that act on a patient's behalf are preserving the patient's dignity
- ☐ 12. I am ethically obligated to speak out for my patients when they are threatened by harm
- ☐ 13. Nurses that provide information to patients about patient care are acting as patient advocates
- ☐ 14. Patients have varying degrees of ability to advocate for themselves
- ☐ 15. Vulnerable patients need my protection in harmful situations
- ☐ 16. Nurses are acting as advocates when nurses protect the rights of patients to make their own decisions
- ☐ 17. I may suffer risks to my employment when acting as a patient advocate
- ☐ 18. Nurses that speak out on behalf of patients may face retribution from employers
- ☐ 19. I may be punished for my actions by my employer when I inform my patients of their own rights
- ☐ 20. Nurses that speak out on behalf of vulnerable patients may be labeled as disruptive by employers
- ☐ 21. When nurses inform and educate patients about patient rights in the clinical setting, the nurses may place their employment at risk

## APPENDIX D: EMAIL RECRUITMENT LETTER

Dear Colleague,

My name is Virginia Chandlee, and I am a PhD Nursing Student at the University of Texas Medical Branch in Galveston, Texas. The reason for this email is to ask you to participate in a research survey. I am currently working on my dissertation research which is a study of **An Exploratory Study of Pediatric Oncology Nurses' Perceptions of and Advocacy Responses to Ethical Issues in Securing Informed Consent in Adolescent and Young Adult Patients**. I would really appreciate your participation in a 7 to 15 minute survey. I believe my research is important to pediatric oncology nursing and the adolescent young adult population and your participation and perspective would contribute valuable information to this study.

As a pediatric oncology nurse since the late 1980's, I know first-hand how important informed consent and advocacy is for this age group. The purpose of my research study is to explore pediatric oncology nurses' perceptions of ethical issues that may arise in the process of obtaining informed consent in adolescent and young adult patients, ages 16-24 years, and to examine if nurses engage in advocacy on behalf of these patients. My hope is that by studying this topic, attention can be brought to this important subject, and with that, more support for those of us who directly work with and care for this vulnerable adolescent young adult population.

There are few criteria that each participant must meet prior to taking the survey:

- Currently working full or part-time caring for adolescent and young adult pediatric oncology patients in the U.S.
- Read and understand English and have access to the internet
- Be at least 21 years of age
- And possess at least six months experience as a pediatric oncology nurse

Important information that you should know about this survey is that your participation is voluntary and all information you provide will remain anonymous. Opening and completing the survey indicates your consent to participate. You may take this survey on any computer of your choice in any location of your choice. If you wish to end your participation prior to completion of the survey for any reason please simply exit the survey.

Once again, I really appreciate your willingness to participate. If you have questions or concerns about this survey, please feel free to contact me at the email address indicated below.

The University of Texas Medical Branch (UTMB) committee that reviews research on human subjects, the Institutional Review Board (IRB) will answer any questions about your rights as a research subject and take any comments or complaints you may wish to offer. You can contact the UTMB IRB by calling 409-266-9400.

Best regards,

Virginia Chandlee, MSN, RN  
Doctoral Student  
University of Texas Medical Branch at Galveston  
Graduate School of Biomedical Sciences and School of Nursing  
301 University Blvd.  
Galveston, Texas 77555-1029

**Primary Investigator Contact Information:**

Virginia Chandlee  
1 Pinedale Ct.  
Mansfield, TX 76063  
Email: vdchandl@utmb.edu

## **APPENDIX E: IRB APPROVAL LETTER**

### **Institutional Review Board**

301 University Blvd.  
Galveston, TX 77555-0158  
Submission Page

11-Jul-2019

### **MEMORANDUM**

TO: Virginia Chandlee  
Grad School Biomedical Science GSBS9999

FROM: Dwight Wolf, MD  
Chairman, IRB #2

RE: Initial Study Approval

IRB #: IRB # 19-0125

TITLE: An Exploratory Study of Pediatric Oncology Nurses' Perceptions of and Advocacy Responses to Ethical Issues in Securing Informed Consent in Adolescent and Young Adult Patients

DOCUMENTS: Research Protocol Version 1 - May 5, 2019  
Recruitment Email  
Demographic Information and Survey Instruments

The UTMB Institutional Review Board (IRB) reviewed the above-referenced research protocol via an expedited review procedure on **06-Jun-2019** in accordance with 45 CFR 46.110(a)-(b)(1). Having met all applicable requirements, the research protocol is approved. The approval for this research protocol begins on **11-Jul-2019**. Continuing Review for this protocol is not required, as outlined in 45 CFR 46.109.

### **Written documentation of consent is waived in accordance with 45 CFR 46.117(c).**

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

The approved number of subjects/specimens to be enrolled/utilized for this project is **300.00**. If, the approved number needs to be increased, you first must obtain permission from the IRB to increase the approved sample size.

If you have any questions related to this approval letter or about IRB policies and procedures, contact the IRB office via email at [IRB@utmb.edu](mailto:IRB@utmb.edu).

### **General Instructions**

To maintain IRB approval in good standing, please observe the following requirements:

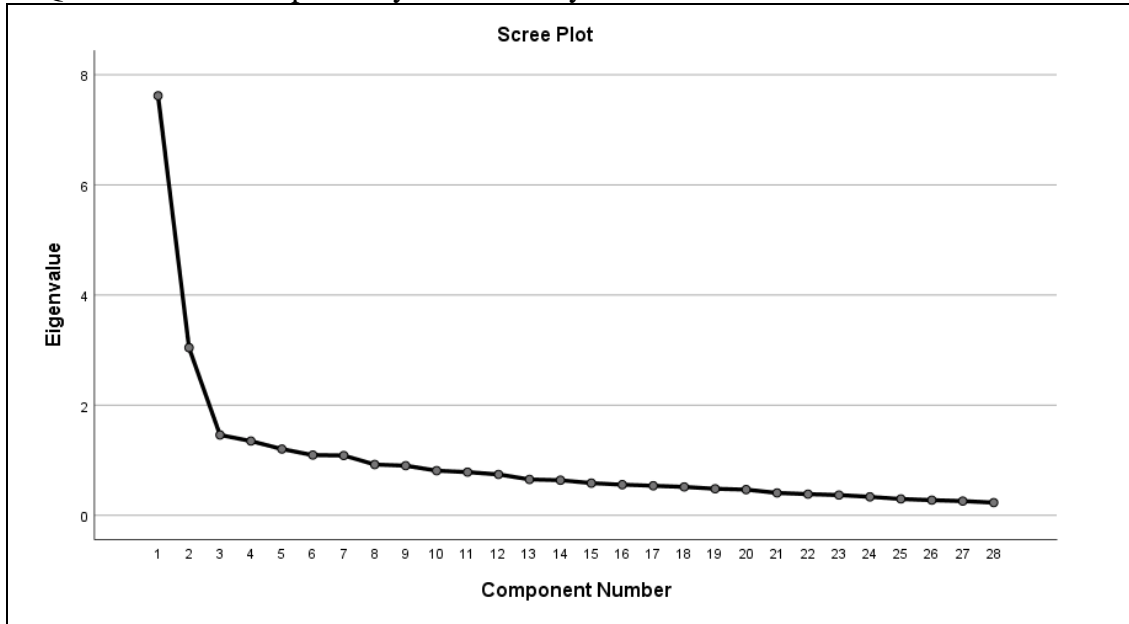
1. Obtain prior IRB approval for any modifications including addition of new recruiting materials, changes in research personnel or site location, sponsor amendments or other changes to the protocol or associated documents. Only those changes that are necessary to avoid an immediate apparent hazard to a subject may be implemented without prior IRB approval.
2. Report all adverse events, protocol violations, DSMB reports, external reports and study closures promptly to the IRB.
3. Make study records available for inspection. All research-related records and documentation may be inspected by the IRB for the purpose of ensuring compliance with UTMB policies and procedures and federal regulations governing the protection of human subjects. The IRB has authority to suspend or terminate its approval if applicable requirements are not strictly adhered to by all research study personnel.
4. When enrolling subjects who do not speak or read English, in research involving therapeutic or prophylactic interventions or invasive diagnostic procedures, a bilingual translator must be continuously available to facilitate communications between research personnel and a subject. If a bilingual translator will not always be available, it may be unsafe for an otherwise eligible candidate to participate in the research if that person does not speak and read English.
5. When enrolling the prisoner population, this study will also require approval from the Texas Department of Criminal Justice (TDCJ) Executive Services in addition to approval from the UTMB IRB. Approval from TDCJ Executive Services must be received prior to the enrollment of offenders or the acquisition or utilization of offender data. Failure to obtain approval from TDCJ Executive Services constitutes non-compliance with UTMB IRB Policies and Procedures. Instructions regarding the submission and approval process may be found at <http://www.tdcj.state.tx.us/>.
6. Close the project once it ends, or when personal identifiers are removed from the data/biospecimens and all codes and keys are destroyed.



# **APPENDIX F: PRELIMINARY FACTOR ANALYSIS FOR NEQ INSTRUMENT**

NEQ Exploratory Factor Analysis -- Preliminary						
Variance Explained						
Component	Initial Eigenvalues			Rotation Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	7.619	27.209	27.209	3.413	12.188	12.188
2	3.044	10.872	38.081	3.244	11.587	23.775
3	1.459	5.210	43.291	2.541	9.074	32.849
4	1.349	4.817	48.107	2.248	8.029	40.878
5	1.203	4.297	52.405	1.868	6.672	47.550
6	1.094	3.907	56.311	1.826	6.521	54.070
7	1.086	3.878	60.189	1.713	6.119	60.189
8	.923	3.296	63.485			
9	.901	3.218	66.703			
10	.810	2.894	69.597			
11	.784	2.801	72.399			
12	.743	2.653	75.052			
13	.651	2.325	77.377			
14	.638	2.277	79.654			
15	.585	2.088	81.742			
16	.557	1.988	83.730			
17	.536	1.916	85.646			
18	.515	1.841	87.487			
19	.482	1.721	89.208			
20	.467	1.668	90.876			
21	.406	1.450	92.326			
22	.385	1.374	93.699			
23	.367	1.311	95.010			
24	.336	1.199	96.209			
25	.297	1.060	97.269			
26	.276	.984	98.253			
27	.258	.922	99.175			
28	.231	.825	100.000			
Extraction Method: Principal Component Analysis.						

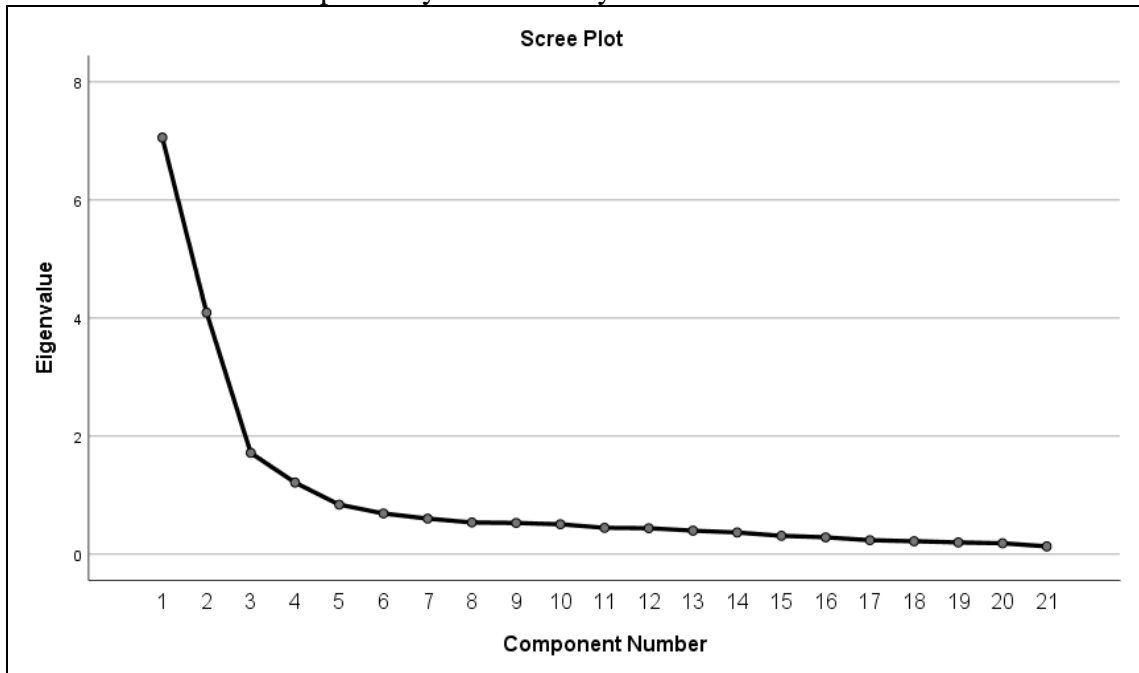
NEQ Scree Plot for Exploratory Factor Analysis



# APPENDIX G: PRELIMINARY FACTOR ANALYSIS FOR PNAS INSTRUMENT

PNAS Exploratory Factor Analysis -- Preliminary						
Total Variance Explained						
Component	Initial Eigenvalues			Rotation Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	7.056	33.602	33.602	4.329	20.616	20.616
2	4.091	19.482	53.084	4.115	19.596	40.213
3	1.715	8.169	61.253	3.058	14.561	54.773
4	1.213	5.778	67.030	2.574	12.257	67.030
5	.839	3.993	71.024			
6	.689	3.283	74.307			
7	.602	2.867	77.173			
8	.537	2.557	79.731			
9	.529	2.517	82.247			
10	.507	2.415	84.663			
11	.447	2.127	86.790			
12	.440	2.096	88.886			
13	.398	1.896	90.782			
14	.367	1.749	92.531			
15	.311	1.483	94.014			
16	.286	1.361	95.375			
17	.237	1.127	96.502			
18	.219	1.044	97.546			
19	.199	.947	98.493			
20	.185	.881	99.373			
21	.132	.627	100.000			
Extraction Method: Principal Component Analysis.						

PNAS Scree Plot for Exploratory Factor Analysis



## REFERENCES

- Abbaszadeh, A., Borhani, F., & Motamed-Jahromi, M. (2013). Nurses' attitudes towards nursing advocacy in the southeast part of Iran. *Journal of Applied Environmental and Biological Sciences*, 3(9), 88–93.
- Adashi, E., Walters, L., Menikoff, J., & Adashi, E. (2018). The Belmont Report at 40: Reckoning with time. *American Journal of Public Health*, 108(10), 1345–1348.  
<https://doi.org/10.2105/AJPH.2018.304580>
- American Academy of Pediatrics, Committee on Bioethics. (2016). Informed consent in decision-making in pediatric practice. *Pediatrics*, 138(2), 1-7.  
doi: <https://doi.org/10.1542/peds.2016-1484>
- American Nurses Association. (2015). *Nursing: Scope and Standards of Practice* (3rd ed.). Silver Spring, MD: ANA.
- Annas, G. J. (2004). *The rights of patients: The authoritative ACLU guide to the rights of patients*. New York: New York University Press.
- Appelbaum, P. S., & Grisso, T. (1988). Assessing patients' capacities to consent to treatment. *The New England Journal of Medicine*, 319(25), 1635-1638.  
<http://dx.doi.org/10.1056/NEJM198812223192504>.
- Applebaum, P. S., & Grisso, T. (2001). *MacArthur competence assessment tool for clinical research (MacCAT-CR)*. Sarasota, FL: Professional Resource
- Baines, P. (2011). Assent for children's participation in research is incoherent and wrong. *Archives of Disease in Childhood*, 96, 960-962.
- Barnes, D. M., Davis, A. J., Moran, T., Portillo, C. J., & Koenig, B. A. (1998). Informed

- consent in a multicultural cancer patient population: Implications for practice. *Nursing Ethics*, 5(5) 412-423.
- Barrett-Sheridan, S. E. (2009). A quantitative correlational study of political behavior and attitudes of nurses toward macro-social patient advocacy. Doctoral Dissertation. Phoenix, AZ: University of Phoenix.
- Beadle, G., Mengersen, K., Moynihan, S., & Yates, P. (2011). Perceptions of the ethical conduct of cancer trials by oncology nurses. *European Journal of Cancer Care*, 20, 585-592.
- Berkman, B. E., Howard, D., & Wendler, D. (2018). Reconsidering the need for re-consent at 18. *Pediatrics*, 142(2), 1-5. <https://doi.org/10.1542/peds.2017-1202>
- Bester, J., Cole, C. M., & Kodish, E. (2016). The limits of informed consent for an overwhelmed patient: Clinicians' role in protesting patients and preventing overwhelm. *AMA Journal of Ethics*, 18(6), 869-886.  
doi: 10.1001/journalofethics.2016.18.9.peer2-1609
- Bishop, A. H., & Scudder, J. R. (2003). Gadw's contribution to our philosophical interpretation of nursing. *Nursing Philosophy*, 4, 104-110.
- Black, L. M. (2011). Tragedy into policy: A quantitative study of nurses' attitudes towards patient advocacy activities. *American Journal of Nursing*, 111(6), 26–35.
- Bleyer A, Viny A, & Barr R. (2006). Introduction in: Cancer epidemiology in older adolescents and young adults 15 to 29 years of age, including SEER incidence and survival: 1975-2000. National Cancer Institute, *NIH Pub. No. 06-5767*, National Institutes of Health, Bethesda, MD.
- Brawner, BM., Volpe, E. M., Stewart, J. M., & Gomes, M. M. (2013). Attitudes and

- beliefs toward biobehavioural research participation. *Annals of Human Biology*, 40(6), 485-495.
- Broome, M. E., & Richards, D. J. (2003). The influence of relationships on children's and adolescents' participation in research. *Nursing Research*, 52, 191-197.
- Bu, X., & Jezewski, M. A. (2007). Developing a mid-range theory of patient advocacy through concept analysis. *Journal of Advanced Nursing*, 57(1), 101-110.
- Candilis, P. J., Fletcher, K. E., Geppert, C. M., Lidz, C. W., & Appelbaum, P. S. (2008). A direct comparison of research decision-making capacity: Schizophrenia/schizoaffective, medically ill, and non-ill subjects. *Schizophrenia Research*, 99(1-3), 350-358. doi:10.1016/j.schres.2007.11.022
- Caplan, A. L. (2007). Challenging teenagers' rights to refuse treatment. *AMA Journal of Ethics*, 9(1), 56-61. doi: 10.1001/virtualmentor.2007.9.1.oped1-0701.
- Centers for Disease Control and Prevention (CDC): USCS Data Visualizations. (2015). Retrieved February 24, 2019, from <https://gis.cdc.gov/Cancer/USCS/DataViz.html>
- Chafey, K., Rhea, M., Shannon, A., & Spencer, S. (1998). Characterizations of advocacy by practicing nurses. *Journal of Professional Nursing*, 14, 43-52.
- Cherry, M. J. (2015). Re-thinking the role of the family in medical decision-making. *Journal of Medicine and Philosophy*, 40(4), 451-472.
- Cherry, M. J. (2017). Adolescents lack sufficient maturity to consent to medical research. *The Journal of Law, Medicine & Ethics*, 45(3), 307-317.
- Choi, P. P. (2015). Patient advocacy: The role of the nurse. *Nursing Standard*, 29(41), 52-58.
- Coleman, D. L., & Rosoff, P. M. (2013). The legal authority of mature minors to general

- medical treatment. *Pediatrics*, 131, 786-793.
- Corbie-Smith, G., Thomas, S. B., & St. George, D. M. (2002). Distrust, race, and research. *Archives of Internal Medicine*, 162(21), 2458–2463.
- Davoodvand, S., Abbaszadeh, A., & Ahmadi, F. (2016). Patient advocacy from the clinical nurses' viewpoint: A qualitative study. *Journal of medical ethics and history of medicine*, 9, 5.
- Department of Health and Human Services: Protection of Human Subjects: Informed Consent. Washington, DC, Federal Registry, January 27, 1981, Part IX. 45 CFR §46. <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm/#46.116>
- DeVellis, R.F. (2017). *Scale Development: Theory and applications* (4<sup>th</sup> ed). Los Angeles: Sage Publications.
- de Vries, M. C., Houtlosser, M., Wit, J. M., Engberts, D. P., Bresters, D., Kaspers, G. J., & van Leeuwen, E. (2011). Ethical issues at the interface of clinical care and research practice in pediatric oncology: a narrative review of parents' and physicians' experiences. *BMC medical ethics*, 12, 18. <https://doi.org/10.1186/1472-6939-12-18>
- Dunn, L. B., Nowrangi, M. A., Palmer, B. W., Jeste, D. V., & Saks, E. R. (2006). Assessing decisional capacity for clinical research or treatment: A review of instruments. *American Journal of Psychiatry*, 163(8), 1323-1334.
- Field, M. J., & Behrman, R. E. (2004). D, Glossary, Acronyms, and Laws and Regulations. In *Ethical conduct of clinical research involving children*. Washington, D.C.: National Academies Press. doi:<https://www.ncbi.nlm.nih.gov/books/NBK25564/>



- Fisher, C. B. (2003). A goodness-of-fit ethic for child assent to non-beneficial research. *American Journal of Bioethics*, 3(4), 27–28.
- Flory, J., & Emanuel, E. (2004). Interventions to Improve Research Participants' Understanding in Informed Consent for Research: A Systematic Review. *JAMA*, 292(13), 1593–1601. <https://doi.org/10.1001/jama.292.13.1593>
- Foley, B., Minick, P., & Kee, C. (2000). Nursing advocacy during a military operation. *Western Journal of Nursing Research*, 22, 492-507.
- Frankel, L. R., Goldworth, A., Rorty, M.V., Silverman, W.A., (eds). (2005). *Ethical Dilemmas in Pediatrics: Cases and Commentaries*. New York, NY: Cambridge University Press.
- Freimuth, V. S., Quinn, S. C., Thomas, S. B., Cole, G., Zook, E., & Duncan, T. (2002). African Americans' views on research and the Tuskegee Syphilis Study. *Social Science and Medicine*, 52(5), 797–808.
- Gadow, S. (1980). Existential advocacy: Philosophical foundation of nursing. In: *Nursing: Images and Ideals, Opening Dialogue with the Humanities* (eds S.F. Spicker & S. Gadow), 79–101. New York: Springer
- Gadow, S. (1989a). An ethical case for patient self-determination. *Seminars in Oncology Nursing*, 5, 99–101.
- Gadow, S. (1989b). Clinical subjectivity advocacy with silent patients. *Nursing Clinics of North America*, 24(2), 535–541.
- Garner, B. (Ed.). (2000). *Black's law dictionary* (7th ed.). St. Paul, MN: West Group Publishing.
- Gerber, L. (2018). Understanding the nurse's role as a patient advocate. *Nursing*, 8(4),

55-58. doi: 10.1097/01.NURSE.0000531007.02224.65

Grace, P. (2001). Professional advocacy: Widening the scope of accountability. *Nursing*

*Philosophy*, 2(2), 151-162.

Grisso, T., & Appelbaum, P. S. (1998). *MacArthur competence assessment tool for*

*treatment (MacCAT-T)*. Sarasota, FL: Professional Resource.

Haylock, P. J. (2015). Cancer survivorship advocacy. *Seminars in Oncology Nursing*,

31(1), 79–85.

Hanks, R. G. (2008a). The lived experience of nursing advocacy. *Nursing Ethics*, 15(4),

468-477. doi:10.1177/0969733008090518

Hanks, R. G. (2008b). *Protective Nursing Advocacy Scale*. Doctoral dissertation.

Galveston, TX: University of Texas Medical Branch.

Hanks, R. G. (2010). Development and testing of an instrument to measure protective

nursing advocacy. *Nursing Ethics*, 17(2), 255–267.

Hein, I. M., Troost, P. W., Lindeboom, R., de Vries, M. C., Zwaan, C. M., &

Lindauer, R. J. (2012). Assessing children's competence to consent in research by  
a standardized tool: a validity study. *BMC Pediatrics*, 12, 156.

Hein I. M., Troost, P. W., Lindeboom, R., Benninga, M. A., Zwaan, C. M., van

Goudoever, J. B., Lindauer, R. J. (2014). Accuracy of the MacArthur Competence

Assessment Tool for Clinical Research (MacCAT-CR) for Measuring Children's

Competence to Consent to Clinical Research. *JAMA Pediatrics*, 168(12), 1147–

1153. doi:10.1001/jamapediatrics.2014.1694

Hein, I. M., Troost, P. W., Broersma, A., de Vries, M. C., Daams, J. G., & Lindauer, R. J.

(2015a). Why is it hard to make progress in assessing children's decision-making

- competence? *BMC Medical Ethics*, 16, 1. doi:10.1186/1472-6939-16-1
- Hein, I. M., Troost, P. W., Lindeboom, R., Christiaans, I., Grisso, T., van Goudoever, J. B., & Lindauer, R. J. (2015b). Feasibility of an Assessment Tool for Children's Competence to Consent to Predictive Genetic Testing: a Pilot Study. *Journal of Genetic Counseling*, 24(6), 971–977. doi:10.1007/s10897-015-9835-7
- Hewitt, J. (2002). A critical review of the arguments debating the role of the nurse advocate, *Journal of Advanced Nursing*, 37(5), 439-445.
- Hickey, K. (2007). Minor's rights in medical decision making. *JONA's Healthcare Law, Ethics, and Regulations*, 9(3) 100-104.
- Higgins, P.A. & Daly, B. J. (2002). Knowledge and beliefs of nurse researchers about informed consent principles and regulations. *Nursing Ethics*, 9(6), 663-671.
- Holder, A. R. (2010). From chattel to consenter: Adolescents and informed consent, 2009 Grover Powers Lecture. *The Yale Journal of Biology and Medicine*, 83(1), 35-41.
- Institute of Medicine. (2004). *The ethical conduct of clinical research involving children*. Washington, DC: National Academies Press. <https://doi.org/10.17226/10958>
- Institute of Medicine. (2009). *Committee on Health Research and the Privacy of Health Information: The HIPAA Privacy Rule*; Nass S. J., & Levit, L. A., Gostin, L.O., (eds). *Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research*. Washington (DC): National Academies Press.
- Joffe, S, Fernandez, C.V., Pentz, R. D., Ungar, D. R., Mathew, N.A., Turner, C. W., Alexandri, A. J., Woodman, C. L., Singer, D. A., & Kodish, E. (2006). Involving children with cancer in decision-making about research participation. *Journal of Pediatrics*, 149(6), 862-868. doi:10.1016/j.jpeds.2006.08.027

- Joffe, S., Cook, E. F., Cleary, P. D., Clark, J. W., & Weeks, J. C. (2001a). Quality of informed consent: a new measure of understanding among research subjects. *Journal of the National Cancer Institute*, 93, 139–47.
- Joffe, S., Cook, E. F., Cleary, P. D., Clark, J. W., & Weeks, J. C. (2001b). Quality of informed consent in cancer clinical trials: a cross-sectional survey. *Lancet*, 358, 1772-1777.
- Josse-Eklund, A., Jossebo, M., Sandin-Bojö, A. K., Wilde-Larsson, B., Petzäll, K. (2014). Swedish nurses' perceptions of influencers on patient advocacy: A phenomenographic study. *Nursing Ethics*, 21(6), 673–683.
- Kalaitzidis, E., & Jewell, P. (2015). The concept of advocacy in nursing: a critical analysis. *Health Care Management*, 34(4), 308–315.
- Katz, A. L., & Webb, S. A., (2016). American Academy of Pediatrics, committee on bioethics: Informed consent in decision-making in pediatric practice. *Pediatrics*, 138(2), 1–16.
- Keegan, T. H., Ries, L. A., Barr, R. D., Geiger, A. M., Dahlke, D. V., Pollock, B. H., & Bleyer, W. A. (2016). Comparison of cancer survival trends in the United States of adolescents and young adults with those in children and older adults. *Cancer*, 122(7), 1009-1016. doi:10.1002/cncr.29869
- Klein, C. C., Jolson, M. B., Lazarus, M., Masterson, B., Blom, T. J., Adler, C. M., Del Bello, M. P., & Strakowski, S. M. (2019). Capacity to provide informed consent among adults with bipolar disorder, *Journal of Affective Disorders*, 242, 1-4.
- Knoppers, B. M., Senecal, K., Boisjoli, J., Borry, P., Cornel, M. C., Fernandez, C. V., Grewal, J., Holm, I. A., Nelson, E., Pinxten, W., Shabani, M., Tasse, A. M.,

- Zawati, M., & Wright Clayton, E. (2016). Re-contacting pediatric research participants for consent when they reach the age of majority. *IRB: Ethics & Human Research*, 38(6), 1–9.
- Kodish E. (2003a). *Assent and Informed Parental Permission: Insights from the PIC*. Presentation to the Committee on Clinical Research Involving Children. Washington, DC: Institute of Medicine.
- Kodish E. (2003b). Informed consent for pediatric research: Is it really possible? *Journal of Pediatrics*, 142(2), 89–90.
- Kon, A. A., & Klug, M. (2006). Methods and practices of investigators for determining participants' decisional capacity and comprehension of protocols. *Journal of Empirical Research on Human Research Ethics*, 1(4), 61–68. doi: 10.1525/jer.2006.1.4.61.
- Koyfman, S. A., Agre, P., Carlisle, R., Classen, L., Cheatham, C., Finley, J. P., Kuhrik, N., Kuhrik, M., et al. (2013). Consent form heterogeneity in cancer trials: The cooperative group and institutional review board gap. *Journal of the National Cancer Institute*, 105(13), 947–953. doi.org/10.1093/jnci/djt143
- Levine, R. J. (2008). Research involving adolescents as subjects: Ethical considerations. *Ann NY Academic Science*, 1135, 280–286.
- Lincoln, Y. S., & Guba, E. G. (1985). *Naturalistic Inquiry*. London: Sage Publications.
- Lidz, C. W., Appelbaum, P. S., Grisso, T., et al. (2004). Therapeutic misconception and the appreciation of risks in clinical trials. *Social Science Medicine*, 58, 1689–1697.
- Madden, L., Shilling, V., Woolfall, K., Sowden, E., Smyth, R. L., Williamson, P. R., & Young, B. (2016). Questioning assent: how are children's views included as

- families make decisions about clinical trials? *Child: care, health and development*, 42(6), 900–908. <https://doi.org/10.1111/cch.12347>
- Mayer, D. K. (1985). Information in *Handbook of Oncology Nursing*, Johnson, B. L. & Gross, J. (eds). New York: Wiley.
- McCabe, M. A. (1996). Involving children and adolescents in medical decisions making: developmental and clinical considerations. *Journal of Pediatric Psychology*, 21(4), 505-516.
- Menikoff, J., Kaneshiro, J., & Pritchard, I. (2017). The common rule, updated. *The New England Journal of Medicine*, 376(7), 613–615.
- Mercurio, M. R., Adam, M. B., Forman, E. N., Ladd, R. E., Ross, L. F., Silber, T. J. (2008). American Academy of Pediatrics policy statements on bioethics. *Pediatrics in Review*, 29 (1) 1-8. doi:10.1542/pir.29-1-e1
- Miller, K. D., Siegel, R. L., Lin, C. C., Mariotto, A. B., Kramer, J. L., Rowland, J. H., Stein, K. D., Alteri, R., & Jemal, A. (2016). Cancer treatment and survivorship statistics, *CA: A Cancer Journal for Clinicians*, 66, 271-289.
- National Cancer Institute. (2016). *Children's Assent*. Retrieved December 1, 2016, from <https://www.cancer.gov/about-cancer/treatment/clinical-trials/patient-safety/childrens-assent>.
- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979). *The Belmont report: Ethical principles and guidelines for the protection of human subjects of research: Appendix*. Bethesda, MD: US Dept. of Health and Human Services, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

- Newman, A. R., Haglund, K., & Rodgers, C. C. (2019). Pediatric oncology nurses' perceptions of prognosis-related communication: A qualitative report. *Nurs Outlook*, 67(1): 101–114. doi:10.1016/j.outlook.2018.11.001
- Noone, A. M., Howlader, N., Krapcho, M., Miller, D., Brest, A., Yu, M., Ruhl, J., Tatalovich, Z., Mariotto, A., Lewis, D. R., Chen, H. S., Feuer, E. J., & Cronin, K. A., (eds). (2017). SEER cancer statistics review, 1975-2017, *National Cancer Institute, Bethesda, MD*. [https://seer.cancer.gov/csr/1975\\_2017noone](https://seer.cancer.gov/csr/1975_2017noone)
- Nunnally, J., & Bernstein, I. (1994). *Psychometric theory* (3rd ed.). New York: McGraw-Hill Publishing.
- Olds, R. S. (2003). Informed consent issues with adolescent health behavior research. *American Journal of Health Behavior*, 27(1), 248-263. doi:10.5993/ajhb.27.1.s3.9
- Parsons, H. M., Schmidt, S., Harlan, L. C., Kent, E. E., Lynch, C. F., Smith, A. W., & Keegan, T. H. (2014). Young and uninsured: Insurance patterns of recently diagnosed adolescent and young adult cancer survivors in the AYA HOPE study. *Cancer*, 120(15), 2352-2360. doi:10.1002/cncr.28685
- Parsons, H. M., Harlan, L. C., Seibel, N. L., Stevens, J. L., & Keegan, T. H. (2011). Clinical trial participation and time to treatment among adolescents and young adults with cancer: Does age at diagnosis or insurance make a difference? *Journal of Clinical Oncology*, 29(30), 4045–4053. doi: 10.1200/JCO.2011.36.2954
- Pedhazur, E., & Schmelkin, L. (1991). *Measurement, design, and analysis: an integrated approach*. Hillsdale, NJ: Lawrence Erlbaum Associates, Inc.
- Polit, D. F., & Beck, C. T. (2014). *Essentials of nursing research: Appraising evidence*

- for nursing practice*. Philadelphia: Wolters Kluwer/Lippincott, Williams, and Wilkins.
- Portney, L. G., & Watkins, M. P. (2009). *Foundations of clinical research: Applications to practice*. Upper Saddle, NJ: Pearson Prentice Hall.
- Poston, R. D. (2016). Assent described: Exploring perspectives from the inside. *Journal of Pediatric Nursing*, 31(6), 353-365.
- Presidential Commission for the Study of Bioethical Issues. (2013). *Safeguarding children: Pediatric medical countermeasure research*. Washington, DC: U.S. Department of Health and Human Services, p. 26.
- Quinn, S. C., Garza, M. A., Butler, J., Fryer, C. S., Casper, E. T., Thomas, S. Barnard, D., Kim, K. H. (2012). Improving Informed Consent with Minority Participants: Results from Researcher and Community Surveys. *Journal of Empirical Research on Human Research Ethics*, 7(5), 44–55. doi: 10.1525/jer.2012.7.5.44
- Ramos, A. M., Devos-Barlem, E. L., Tomaschewski-Barlem, J. G., Rocha, L. P., Silva Da Silveira, R., & Pereira, L. A. (2018). Healthcare advocacy and moral distress in the practice of nurses. *International Archives of Medicine*, 11(37), 1-11.  
doi:10.3823/2578
- Raosoft.com. (2018). *Sample Size Calculator*. [online] Available at:  
<<http://www.raosoft.com/samplesize.html>> [Accessed 8 November 2018].
- Rebers, S., Aaronson, N. K., van Leeuwen, F. E., & Schmidt, M. K. (2016). Exceptions to the rule of informed consent for research with an intervention. *BMC Medical Ethics*, 17, 9. <https://doi.org/10.1186/s12910-016-0092-6>
- Rosse, P. A., & Krebs, L.U. (1999). The nurse's role in the informed consent process.



- Seminars in Oncology Nursing*, 15(2), 116-123.
- Ruccione, K. S. (1994). Informed consent in pediatric oncology: A nursing perspective. *Journal of Pediatric Oncology Nursing*, 11(3), 128-133.
- Ruccione, K. S., Kramer, R. F., Moore, I. K., & Perin, G. (1991). Informed consent for treatment of childhood cancer: Factors affecting parents' decision making. *Journal of Pediatric Oncology Nursing*, 8, 112-121.
- Santelli, J., Haerizadeh, S., & McGovern, T. (2017). Inclusion with protection: Obtaining informed consent when conducting research with adolescents, *Innocenti Research Brief 2017 – 05 Methods: Conducting Research with Adolescents in Low- and Middle-Income Countries*, no.3, UNICEF Office of Research – Innocenti, Florence.
- Schlam, L., & Wood, J. P. (2000). Informed consent to the medical treatment of minors: Law and practice. *Health Matrix: The Journal of Law-Medicine Case Western Reserve University*, 10(2) 141-172.
- Selanders, L. C., & Crane, P. C. (2012). The voice of Florence Nightingale on advocacy. *Online Journal of Issues in Nursing*, 17(1), 1.  
<https://doi-org.libux.utmb.edu/10.3912/OJIN.Vol17No01Man01>
- Sibley, A., Fitzpatrick, R., Davis, E., Sheehan, M., & Pollard, A. (2018). The family context of assent: Comparison of child and parent perspectives on familial decision-making. *Children & Society*, 32(4), 266–278.  
<https://doi.org/10.1111/chso.12250>
- Siegel, R. L., Miller, K. D., & Jemal, A. (2018). Cancer statistics, 2018. *CA: A Cancer Journal for Clinicians*, 68(1), 7-30. doi:10.3322/caac.21442

- Sharp, S. M. (2004). Consent documents for oncology trials: Does anybody read these things? *American Journal of Clinical Oncology*, 27(6), 570–575.
- Steinberg, L. (2013). Does recent research on adolescent brain development inform the mature minor doctrine? *Journal of Medicine and Philosophy*, 38, 256-267.  
doi:10.1093/jmp/jht017
- Sudore, R., Landefeld, C., Williams, B., Barnes, D., Lindquist, K., & Schillinger, D. (2006). Use of a modified informed consent process among vulnerable patients: a descriptive study. *Journal of General Internal Medicine*, 21(9), 1009–1009.  
doi:10.1007/bf02743161
- Thacker, K. S. (2008). Nurses' advocacy behaviors in end-of-life nursing care. *Nursing Ethics*, 15(2), 174.
- The National Academies. (2004). *Ethical Conduct of Clinical Research Involving Children*. Washington D.C.: Institute of Medicine of the National Academies.
- Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No.10. (1949). 2, 181-182. Washington, D.C.: U.S. Government Printing Office.  
[https://archive.org/stream/trialsofwarcrimi15inte/trialsofwarcrimi15inte\\_djvu.txt](https://archive.org/stream/trialsofwarcrimi15inte/trialsofwarcrimi15inte_djvu.txt)
- Toda, Y., Sakamoto, M., Tagaya, A., Takahashi, M., & Davis, A. J. (2015). Patient advocacy: Japanese psychiatric nurses recognizing necessity for intervention. *Nursing Ethics*, 22,7.
- Tomajan, K. (2012). Advocating for nurses and nursing. *The Online Journal of Issues in Nursing*, 17(1), 4.
- Unguru, Y., Sill, A. M., & Kamani, N. (2010). The experiences of children enrolled in

- pediatric oncology research: Implications for assent. *Pediatrics*, 125(4), 876-883.
- U.S. Department of Health and Human Services, Health Resources and Services Administration, National Center for Health Workforce Analysis. (2019). *Brief Summary Results from the 2018 National Sample Survey of Registered Nurses*, Rockville, Maryland.
- US Department of Health and Human Services. (rev. 2009). Code of Federal Regulations. *Protection of human subjects: Informed consent*. Washington, DC, Federal Registry, Part IX. Title 45 CFR part 46.
- <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm/#46.116>
- Varricchio, C. G., & Jassak, P. F. (1989). Informed Consent: An Overview. *Seminars in Oncology Nursing*, 5(2), 95-98.
- Weisleder, P. (2004). The rights of minors to confidentiality and informed consent. *Journal of Child Neurology*, 19(2), 145-148. doi:10.1142/7914
- Weithorn, I. A., & Campbell, S. B. (1982). The competency of children and adolescents to make informed treatment decisions. *Child Development*, 53(6), 1589-1598.

## **Vita**

Virginia Diane Oppermann was born in Galveston, Texas, on November 10, 1963 to Theodore Joseph and Juanita Oppermann, and was the oldest of six children (four boys and two girls). She married Kevin Joseph Chandlee on October 21, 1989, in North Brunswick, NJ, and has been happily married for more than 30 years. Virginia graduated from St. Mary's College, South Bend, IN in May of 1986 with a Bachelor of Science degree in Nursing. She moved to New York City and began working at Memorial Sloan Kettering Cancer Center (MSKCC) in June of 1986 on the pediatric oncology unit as a Graduate Nurse. In spring of 1987, Virginia began her MSN in Pediatric Primary Care at Seton Hall University, East Orange, NJ. While working on her advanced degree, she ascended the clinical ladder at MSKCC as a CNII, CNIII, and CNIV. When she graduated from Seton Hall in May 1991, she became the Unit Nurse Clinician on the same inpatient pediatric oncology unit. She also began teaching as an adjunct professor in Pediatrics, Maternity, and Medical Surgical Nursing at Iona College in the Associate's Degree of Nursing evening program in New Rochelle, NY, which she continued through May of 1995. In January 1995, Virginia began working at White Plains Hospital in White Plains, NY in the float pool after leaving MSKCC the prior summer. In 2001, after moving with her family to New Jersey, Virginia worked for a short time at Warren Hospital in Phillipsburg, NJ in maternal child health before relocating to Mansfield, TX in 2002. From 2003 to 2012, Virginia worked in Mansfield ISD as a school nurse, first in an elementary school then as the district travel nurse. In July 2011, Virginia joined the faculty of Tarrant County College in Fort Worth, TX, as an adjunct professor in

Pediatrics and Foundation Skills, where she currently remains as an adjunct. In addition, in July 2011, Virginia began working at JPS Health Network in Fort Worth, TX, the Tarrant County Hospital system, and has remained there for the last nine years in the Academic Affairs department overseeing nursing, allied health, research, and medical students completing clinical rotations within the network. She currently manages a team of eight, including both clinical coordinators and clinical instructors. In August 2014, Virginia entered the Doctoral Graduate program in Nursing at UTMB, Galveston, TX.

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