Pain Management and Comfort in Robotic Laparoscopic Prostatectomy Patients

A Thesis

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by

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of the requirements

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Dedication

I would like to dedicate my dissertation work to my husband, Glenn, without whom, I may not be on the same path as I am today. My husband has always shown me encouragement and provided support throughout my educational journey. My husband has been there to pick up the slack as I spent many hours working toward my Doctoral Degree.

The strong work and commitment which has brought me to this point in my life is a reflection of my grandmother Elizabeth Gilmore. In remembrance of her beautiful personality, strong will, kindness and commitment to get things done, I will eternally be grateful for such a positive role model, many thanks to my Nan!

Also, I would like to thank all of the men who so willingly participated in my research during a difficult journey of their own with a cancer diagnosis. I am so grateful for the time they allowed me while undergoing their procedure and in the recovery phase of their care.

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Abstract

Pain Management and Comfort in Robotic Laparoscopic Prostatectomy Patients

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Prostate cancer is the second most common cancer in American men with about 1 in 7 men being diagnosed during his lifetime. Robotic surgery has been increasing since its inception over 10 years ago and these procedures continue to grow and diversify. A focus on pain control, reducing invasiveness and promoting early discharge is a benefit and goal with use of Robotic Procedures. Pain assessment and management has become a priority to many stakeholders including medical caregivers, patients, health care organizations and credentialing agencies. Although pain is reduced in minimally invasive surgery, there is a gap in the literature describing pain and comfort management. A variety of pharmacologic agents have been used to treat pain and improve comfort in this population. Pain control modalities and treatments in this research focus specifically on pharmacologic modalities. Two groups were formed to differentiate use of opioids in Group A and opioids plus alpha 2 agonist in Group B. After a standard of care for each patient, pain and comfort levels were measured and medical records were reviewed. Participants were placed into Group A or B depending upon their medications received. The null hypothesis of this research is that there will be no difference between two standard anesthesia protocols with regard to pain and comfort in the perioperative setting and decreased pain will not be associated with increased comfort. Data collection ceased upon completion of both groups and statistical analysis revealed no significant difference between Group A and Group B.

Chapter 1: Introduction and Overview

Introduction

Pain assessment and management has become a priority to many stakeholders including medical caregivers, patients, health care organizations and credentialing agencies. "Pain is whatever the experiencing person says it is, existing whenever the experiencing person says it does" (McCaffery & Beebe, 1989, p. 7). The Joint Commission (TJC) began including pain control as a part of the national standards and accreditation process (TJC, 2009). California has passed regulations regarding pain as the 5th vial sign (State of California Department of Consumer Affairs, 2000) and the Veterans Administration published a 57 page toolkit implementing a Veteran Health Administration (VHA) National Pain Management Strategy to promote pain as the 5th vital sign and offer guidelines for comprehensive pain assessment (Department of Veteran Affairs, 2000). Delayed hospital discharge and patient recovery from surgery has been associated with under treatment of postoperative pain (Pyati & Gan, 2007). Further, pain plays a significant role in consumer satisfaction. Consumer satisfaction is a growing interest which is important to all stakeholders, including health care providers. Consumers satisfaction with care related to pain and comfort have been shown to be highly correlated to scores on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey with a Cronbach's alpha, 0.94, and correlation coefficient 0.84 for communication and adequate pain control (Jha, Orav, Zheng & Epstein, 2008).

An early goal of nursing has been to provide comfort to patients. The General Comfort Questionnaire was used as part of this research and was developed by Dr. Kolcaba into a Comfort Theory which was first published in 1994. Wilson and Kolcaba (2004), describe a comfort theory relating to nursing which depicts the importance for enhanced comfort in

patients. Comfort has many meanings and connotations; it is much more than ease or relief of discomfort. Holistic comfort may include physical, psychospiritual, sociocultural, and environmental needs (Wilson & Kolcaba, 2004). Comfort is defined as "the immediate state of being strengthened through having the human needs for relief, ease, and transcendence (types of comfort) addressed physically, psychospiritually, socioculturally, and environmentally" (contexts in which comfort is experienced) (Kolcaba, 2003, p. 251).

Although pain is reduced in minimally invasive surgery, there is a *gap* in the literature describing pain and comfort management with therapeutic regimens. Therapeutic regimens are recommended plans of care. This may be a protocol for pain management, such as specific groups of medications found to be most effective for care during surgery. A wide array of pharmacologic agents may be used independently or combined for pain control and comfort. Variation of pharmacologic selections may be practitioner dependent. Optimizing pain control and comfort levels are key issues important in facilitating a rapid recovery and patient discharge.

Overview

Approximately one man in seven will be diagnosed with prostate cancer during his lifetime (American Cancer Society, 2014). Cancer estimates for 2015 include about 220,800 new cases of prostate cancer diagnosed with about 27,540 deaths (American Cancer Society, 2014). Prostate cancer is the second most common cancer in American men only to skin cancer and the second leading cause of cancer death behind only lung cancer (American Cancer Society, 2014). About one man in thirty-six will die of prostate cancer; however, this type of cancer is very treatable and more than 2.5 million men in the United States with prostate cancer diagnosis are still alive today (American Cancer Society, 2014).

Seventy five million Americans suffer from serious or severe pain and 50 million of those people endure chronic daily pain serious enough to affect their quality of life (Yass, 2009). The American Pain Society has created a mission to serve people in pain through advancing research, education, treatment, and professional practice (American Pain Society, 2015). The under treatment of pain in today's society is not justified. With a growing trend toward laparoscopic procedures, specifically robotic laparoscopic; it is important to determine the effectiveness of pain and comfort in the peri-operative period. Pain management and comfort are important goals to achieve in order to facilitate and improve patient care and outcomes. Pain control modalities and treatments in this research proposal focus specifically on pharmacologic modalities used in the Operating Room (OR) and Post Anesthesia Care Unit (PACU).

Opioid Sparing

Opioid sparing is a strategy used to reduce side effects of medications (Wheeler, Oderda, Ashburn & Lipman, 2002). A non-opioid medication used in combination with opioids to reduce opioid requirements is considered opioid-sparing and can provide up to 20-50% opioid sparing effects (Kehlet, 2005). Significant side effects of opioids can interfere with recovery and reduce a patient's comfort level (Kehlet, 2005). Using opioid dose sparing strategies assists in alleviating harsh side effects (Wheeler, Oderda, Ashburn & Lipman, 2002). Multimodal balanced analgesia applies the opioid sparing technique leading to a reduction in adverse effects of opioids (Kehlet, 2005). The Joint Commission has set a standard for pain management to reduce patients' pain (Kehlet, 2005). If this goal is achieved though opioids alone, there is an increased risk of adverse effects (Kehlet, 2005). Although the National Institute of Health (NIH) practice guidelines suggest opioids be the primary mode of analgesia, concerns related to adverse effects are significant (Wheeler, Oderda, Ashburn & Lipman, 2002). Many studies have shown

the benefits of multimodal analgesia with a variety of differing cases; however; there is limited information on this approach after robotic surgery.

Multimodal Analgesia

Pain control modalities and treatments in this research study focus specifically on pharmacologic modalities. Multimodal Analgesia is one of these modalities. Multimodal analgesia allows for a combination of pharmacologic agents use therefore improving effectiveness and reducing side effects of larger doses of any individual agent (White, 2010). Multimodal therapy combines analgesics with differing mechanisms of action to create a synergistic effect, thereby reducing total doses of each drug (Kamming, Chung, Williams, McGrath & Curti, 2004). A variety of medications may provide postoperative analgesia. Analgesia is defined as the insensibility of pain without loss of consciousness (Merriam-Webster, 2010). Many different combinations of pharmacologic agents may be used to produce analgesia, including local anesthetics, opioids, and alpha-2 agonists. Dexmedetomidine is an alpha-2 adrenergic agonist which provides sedation while decreasing anesthetic use without respiratory depression (Davis, Waters, Vinson, Eddy & Vick, 2000). Although opioids reduce pain, side effects associated with these agents may contribute to discomfort (Wu, et al., 2005). Multimodal analgesia or opioid sparing is a technique of pain management aimed to improve analgesia's safety and efficacy through combining analgesic agents of different drug classes in order to reduce dosing of opioids and side effects of these individual medications (White & Kehlet, 2010). Multimodal balanced analgesia can help to reduce adverse outcomes generally associated with opioids alone (White & Kahlet, 2010). Rationale for multimodal analgesia is to reduce the dose of each analgesic which improves anti-nocioception due to synergistic or additive effects; this may reduce the severity of side effects (Kehlet & Dahl, 1993). Non opioid analgesics are

used for multimodal analgesia in order to reduce opioid requirements (White & Kahlet, 2010; Wheeler, Oderda, Ashburn & Lipman, 2002). Agents such as NSAIDs, *N*-Methyl-D-aspartate receptor antagonist (Ketamine), Acetaminophen, local analgesics and alpha-2 agonists may reduce the total dose of opioids thereby reducing potential side effects (Pyati & Gan, 2007). The goal of multimodal analgesia is opioid sparing which reduces postoperative morbidity and medication related complications (White, Kehlet & Liu, 2009; Classen, Pestotnik, Evans, Lloyd, & Burke 1997). Combining analgesics from differing drug classes improves safety and efficacy through the variety of each drugs mechanism of action (White & Kehlet, 2010).

Pharmacologic Agents

A variety of medications may provide postoperative analgesia. Analgesia is defined as the insensibility of pain without loss of consciousness (Merriam-Webster, 2010). Many different combinations of pharmacologic agents may be used to produce analgesia, including local anesthetics, opioids, and alpha-2 agonists (Wheeler, Oderda, Ashburn & Lipman, 2002). Opioids used in this study were fentanyl and hydromorphone. Dexmedetomidine is an alpha-2 adrenergic agonist which provides sedation while decreasing anesthetic use without respiratory depression (Davis, Waters, Vinson, Eddy & Vick, 2000). Dexmedetomidine is the alpha-2 agonist which was used in this study. The medications of interest given in the OR and PACU will have an effect on patient pain and comfort upon awakening from anesthesia in the PACU which is the reason both areas are included in this study. Anesthesia providers are the individuals who determine which medications are given and what dose is required. Due to physiologic implications of the pharmacokinetics and pharmacodynamics of dexmedetomidine combined with surgical implications of positioning and insufflation, this study allowed for provider standard of care in their choice of medication regimen only to be reviewed after

completion of care. Medications were dosed as provider standard of care and totaled in each area representing the cumulative effects of medications given and measuring the effects in the PACU and final measurement in the patient room after discharge from PACU. Although opioids reduce pain, side effects associated with these agents may contribute to discomfort (Wu, et al., 2005). Further, use of local anesthetics at port and incision sites can improve patients' pain and comfort, and further reduce opioid requirements.

The two standards of care anesthetic regimens for this research provide further information on both the multimodal balanced analgesia and opioids alone approach to pain management. Further identification of single agent pain control compared to two agents will guide our practice to the best pain management strategy for this robotic laparoscopic procedure. Therefore the two protocol groups are those participants who received opioids alone and those who received opioids with an α 2 agonist.

Purpose

The *purpose* of this study was to determine the best pain management strategy for this robotic laparoscopic procedure, both improving pain control and comfort for a facilitated recovery and expedited discharge from the hospital. A procedure specific approach to peri-operative pain management is appropriate to optimize multimodal pain management strategies (White & Kehlet, 2010).

The *long-term goal* of this project therefore was to develop a best practice pain management strategy to address the needs of Robotic Assisted Laparoscopic Prostatectomy (RALP) patients' through improvement of comfort and pain control. The *objective* of this study was to identify the relationship of pain management to comfort in this robotic surgical population through comparison of two standards of anesthesia care protocol in the peri-operative setting.

Hypotheses

The specific aims of this project are:

1. Compare the effect of 2 pharmaceutical regimens on pain and comfort in the laparoscopic robotic prostatectomy patient. The null hypothesis: There will be no difference between two standard anesthesia protocols with regard to pain and comfort prior to surgery, admission to PACU after surgery, discharge from PACU, and admission to the Surgical Unit.

2. Explore the relationship between pain and comfort in post-operative RALP patients. The null hypothesis: Decreased pain will not be associated with increased comfort.

Chapter 2: Background and Significance

Cancer Prevalence

According to the World Health Organization (WHO), cancer was a leading cause of death worldwide, with an estimated 7.9 million deaths in 2007 and 8.2 million in 2012 accounting for 13% of all deaths (ACS, 2007; WHO, 2014; ACS, 2014). Projections of cancer death rates by 2050 are estimated to be 17.5 million individuals (ACS, 2014). Early detection of prostate cancer accounts for the increasing rates in the United States with wide use of prostate screening antigen (PSA) testing (ACS, 2008). Early treatment allows for decreasing death rates in developed countries (ACS, 2007). After the age of 50, prostate cancer risk increases exponentially (NCI, 2014). In the United States from 2002-2006, the median age at death for cancer of the prostate was 80 years of age (NCI, 2006). Approximately 0.0% died under age 20; 0.0% between 20 and 34; 0.1% between 35 and 44; 1.4% between 45 and 54; 7.2% between 55 and 64; 20.1% between 65 and 74; 40.9% between 75 and 84; and 30.3% 85+ years of age (NCI, 2006). The prevalence as of January 1, 2006, was approximately 2,177,975 men alive who had a history of cancer of the prostate in the United States (NCI, 2006). Estimates of prostate cancer diagnosis increased from 185,895 men diagnosed in 2005 (CDC, 2009) to 186,320 men diagnosed with prostate cancer in 2008 (ACS, 2008). Deaths from prostate cancer in 2008 were an estimated 28,660 in the United States alone (NCI, 2008).

Robotic Surgery

the historical treatment of prostate cancer.

Treatment modalities range from conservative to aggressive therapy (Bickert & Frickel, 2002). The four main treatment modalities include, but are not limited to radical prostatectomy surgery, radiation therapy, androgen deprivation, or active surveillance with follow up

(Cooperberg, Broering & Carroll, 2009). Standard laparoscopic approach was technically challenging for surgeons due to limited instrumentation, laparoscopic experience, and a significant learning curve (Basillote, Ahlering, Skarecky, Lee & Clayman, 2004). The first robotic civilian procedure was performed in May, 2000, at Frankfurt University (Goldstraw, Patil, Anderson, Dasgupta & Kirby, 2007). The advent of robotic prostate surgery has grown significantly in the past ten years.

robotic assisted laparoscopic prostatectomy: a new surgical treatment.

Laparoscopic surgery alone provides a two dimensional image, non-wristed instruments, poor ergonomics, and counter intuitive motion while robotic surgery improves laparoscopic surgery through three dimensional magnified exposure and robotic instrument tip articulation (Thaly, Patel & Shah, 2006). Robotics improves the ability and performance of complex open and laparoscopic procedures to be performed using small incisions, and reducing complication rates (Ficarra, Cavalleri, Novara, Aragona & Artibani, 2007; Thaly, Patel & Shah, 2006). A high percentage of these complex surgical patients are discharged within 24 to 48 hours after surgery (Ficarra, et. al., 2007; Goldstraw, et. al., 2007; Starnes & Warren-Sims, 2006). A prescription for oral narcotic pain medication is provided upon discharge which many patients only use for a few days (Starnes & Warren-Sims, 2010). As of 2006, there were more than 400 robotic systems in the United States (Murphy, Challacombe, Khan, Dasgupta (2006). Research areas related to pain management in robotic procedures is critical in order to provide the highest quality, most efficient and cost effective care postoperatively (Cleary & Nguyen, 2002).

Although open prostatectomy procedures have been performed for many years, the newer developed technology of robotic surgery has had a significant influence on the treatment of prostate cancer. Robotic surgery allows a better view through three dimensional visualization of

the prostate and can reduce tremor and fatigue and enhance mobility for surgery (Murphy, Challacombe, Khan, Dasgupta, 2006). While robotic outcomes can be favorable, pain control following surgery is an issue which needs to be addressed in this new population. Robotic laparoscopic procedures are recent additions to the expanding surgical options and although the numbers of these procedures have been dramatically increasing, postoperative pain related research is still very limited in this area. Respectively, the need to explore effective pain control regimens is imperative to patient care. The postoperative period includes care during the immediate postoperative period in the operating room and the post anesthesia care unit (PACU), as well as during the days following surgery (Encyclopedia of Surgery, 2010). Although patients are followed by the surgeon for up to one year after the surgery, the immediate postoperative period is the focus of this research (from PACU admission to transfer to medical surgical area).

Pain and Comfort with Robotic Surgery

As the use of robotics continues to grow and diversify, new criteria come to light with a focus on pain control, reducing invasiveness and promoting early discharge. A variety of pharmacologic agents have been used to treat pain and improve comfort in this population. Each patient may have more than one analgesic agent which may be termed "multimodal therapy".

Multimodal therapy combines analgesics with differing mechanisms of action to create a synergistic effect, thereby reducing total doses of each drug (Kamming, Chung, Williams, McGrath & Curti, 2004). This method allows a reduction of opioid requirements and the side effects frequently associated with them (Kamming, et. al., 2004). Analgesia protocols may assist in reducing variance of practice and improve pain management (Kamming, et. al., 2004). The ***purpose*** of this study was to determine the best pain management strategy for this robotic laparoscopic procedure, both improving pain control and comfort for a facilitated recovery and

expedited discharge from the hospital. A procedure specific approach to peri-operative pain management is appropriate to optimize multimodal pain management strategies (White & Kehlet, 2010).

This study provides a scientific base for development of improved pharmacologic pain and comfort interventions for this population. Pain and comfort in this relatively new procedure has not been adequately addressed. This study provides important information about the efficacy of pain management in the immediate postoperative period by comparing two anesthetic regimens for this population. The results could be used to guide future anesthetic practice.

Some research reports a reduction in postoperative pain in laparoscopic prostatectomy procedures, but this has not been measured in robotic surgery (Humphreys, Gettman, Chow, Zincke & Blute, 2004). Further statements of proposed benefits of RALP have included reduced postoperative pain (Goldstraw, et. al., 2007; Starnes & Warren-Sims, 2006). However, robotic assisted laparoscopic prostatectomy (RALP) procedures pain and comfort reports have not been a primary focus of research to date. An investigation of same day surgery reported increased evidence that "inadequately controlled pain after ambulatory surgery is commonplace" (p. 154) with 82% of patients leaving the hospital in pain, 88% having pain in the four day postoperative period, and 35% having moderate to severe pain at home after analgesics (Watt-Watson, Chung, Chan & McGillion, 2004, p. 154). Frequently comfort is reduced after RALP due to insufflation gas, bladder spasm, and foley catheter discomfort (Starnes & Warren-Sims, 2006). Insufflation gas is an irritant to the peritoneum and may cause localized or central hypothermia leading to postoperative pain (Sammour, Kahokehr & Hill, 2008). Further, patients frequently feel abdominal distention (Starnes & Warren-Sims, 2006). Bladder spasms are a common complaint and can be treated with a suppository (Starnes & Warren-Sims, 2006). Foley catheter discomfort

is a patient focus postoperatively which is caused by implantation of the catheter through the urethra which exits at the tip of the penis (Klein, 2008). These uncomfortable issues usually resolve prior to discharge.

Evidence of pharmacologic relationships may improve pain and comfort in this patient population. A variety of medications may provide postoperative analgesia. This study's aim was to find the best combined pharmacologic therapy regimen to improve patient comfort, minimize pain, and safely facilitate an expedient discharge to home. With the significant growth of robotic surgery throughout the United States, it is essential to implement the best pain strategy available (Cleary & Nguyen, 2002). Application of standardized pain evaluation and treatment modalities may lead to improvements in patient care (White & Kehlet, 2010). Nursing plays a key role in delivering quality care using evidenced based practice. Knowledge of analgesic pharmacology and interactions between these agents is imperative in providing excellence in nursing care for robotic surgery patients.

Background Summary

Nursing is challenged with improving quality care and doing it with less time. Patients are being discharged after RALP surgery within 24 hours. Reducing complications while improving comfort and pain control are key factors for an effective strategy to improve patient satisfaction, and facilitate discharge to home. The gap in the literature reviewing therapeutic regimens related to pain management and comfort are important to study with the growing trend of robotic surgery. Reducing side effects and improving pain control and comfort in this population will lead to improved quality of care.

Chapter 3: Design and Methodology

Overall Approach and Rationale

This study was an observational descriptive prospective quantitative study with a convenience sample. This cross sectional study controlled for procedure type. Groups were defined after treatment was complete, ensuring no manipulation of plan of care or treatment strategy. A retrospective chart review was used to determine group placement of participants: Group A or Group B.

Of special note, there was a shift in the screening and treatment for prostate cancer guidelines (ACS, 2010) during the time of this research which dramatically reduced the number of robotic prostate procedures scheduled. This increased the collection time from an estimated one month to nearly five months.

Site Selection

A convenience sample from a Philadelphia institution provided recruitment of subject pool. Fox Chase Cancer Center is located in Northeast Philadelphia, PA.

Population Sample

inclusion criteria.

Adult Male subjects age 18 and older

Those who are scheduled for RALP

Willing to participate in study

Anesthesia standard of care includes opioids with or without α 2 agonist

exclusion criteria.

Dependent upon others to make health care decisions

Participant unable to complete pain and comfort information or if procedure is changed to an open incision.

Applicable group at required statistical participant level

No Opioids used

*RALP = Robotic Assisted Laparoscopic Prostatectomy

Methods

The Primary Investigator (PI) Kimberly Davis performed this research at Fox Chase Cancer Center after a full review and approval by Fox Chase Cancer Center IRB and in collaboration with Drexel University RRC & IRB. Individuals scheduled for RALP at Fox Chase Cancer Center were potential participants for this study. All adult males who met the inclusion criteria were offered the opportunity to participate in this research study. These individuals were approached to offer participation in this study. Informed consent and HIPAA authorization forms were obtained. Candidates were recruited either in the physicians' offices or pre-operatively. Upon the candidates' interest in participation, a full explanation of the research was given and informed consent was obtained. Pre-operatively, the participant was given the Demographic Data Sheet (DDS), The Numerical Rating Scale (NRS) and General Comfort Questionnaire (GCQ) to complete. Postoperatively, within ten minutes of PACU admission and at PACU discharge, the NRS was assessed as standard of care. Final assessments were completed after participants' arrival to medical/surgical room; the NRS and GCQ were repeated. Medical Record was reviewed to determine medications received intra-operatively and in PACU. This placed participant in Group A or B.

Research Setting

Fox Chase Cancer Center is devoted entirely to cancer treatment, research and prevention. This100-bed hospital, located in Philadelphia, has been consistently ranked by *U.S. News and World Report* among the top cancer centers in the nation (Fox Chase Cancer Center, 2014, Press Release). Fox Chase Cancer Center is an independent, nonprofit institution formed in 1974 by the union of American Oncologic Hospital (one the nation's first cancer hospitals, established in 1904) and the Institute for Cancer Research (founded in 1927) (Fox Chase Cancer Center, 2014, Fact Sheet). The Mission of Fox Chase Cancer Center: The mission of Fox Chase is to prevail over cancer, marshaling heart and mind in bold science, breakthrough medicine, and personal touch (Fox Chase Cancer Center, 2014, Mission). Fox Chase Cancer Center, was the first acute care hospital in Pennsylvania and specialty hospital in the country to receive Magnet status, and has been designated for the fourth time in a row — now making it the first hospital in Pennsylvania to have achieved three successful Magnet renewals (Fox Chase Cancer Center 2014, Credentials). Magnet designation is the nation's highest form of recognition for nursing excellence and is one of the benchmarks used to measure the quality of care patients receive (Fox Chase Cancer Center 2014, Credentials).

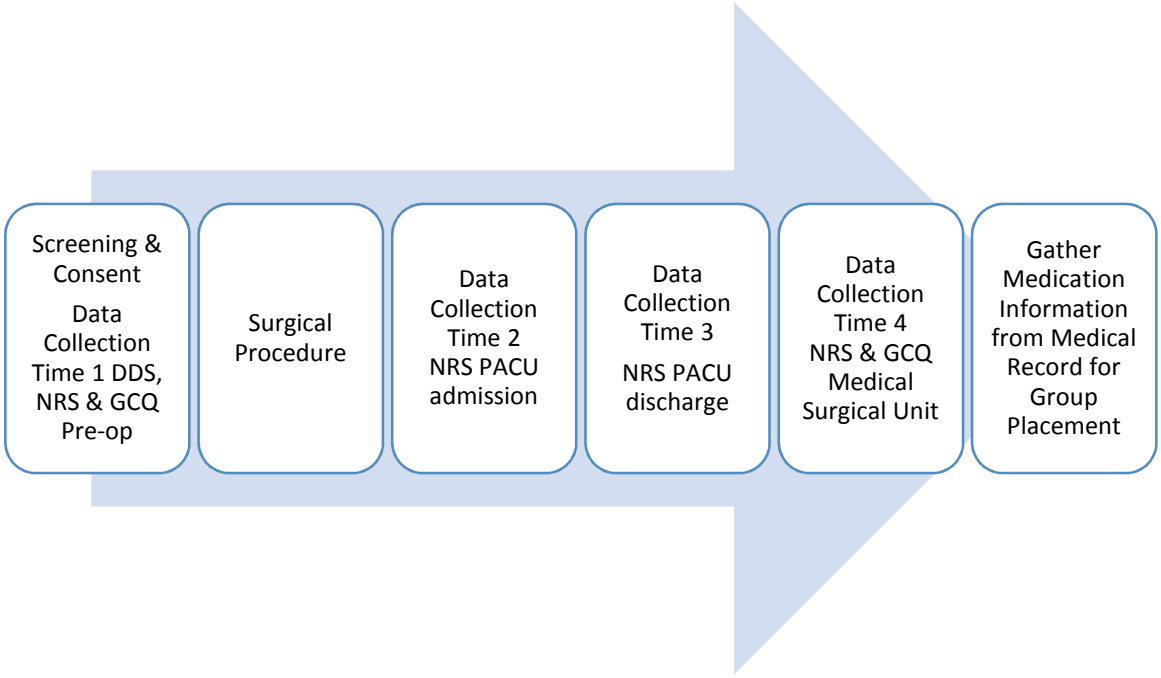

Figure 1 Data Collection Points & Measures

Statistical Considerations

Specific Aim 1 was to explore the effect of 2 groups of pharmaceutical regimens on pain and comfort in the laparoscopic robotic prostatectomy patient. The null hypothesis: Pain and comfort will not vary among the two pharmaceutical regimens.

Group A: Opioids

Group B: Opioids + α 2 agonist

Data were summarized as means and standard deviation for continuous variables and frequencies for categorical and discrete variables. Baseline demographics and preoperative variables were compared by treatment. For the primary outcome, pain and comfort were measured before surgery and at 3 post surgery time points. To test the treatment effect on pain scale score and comfort score, we used a hierarchical linear modeling (HLM) where level 1 is the individual observation repeated over time and level 2 is the individual within which the observations are nested. Compared to a more traditional repeated measure ANOVA, this

maximum likelihood based method will allow us to use all available data the individual provides, even if some of it is missing. The researcher also adjusted for any unbalanced factors that were identified in the preliminary analysis by including them as covariates. The model also included time of the assessment, treatment arm and the interaction between treatment and time. Because this was a pilot study, adjustment for multiple comparisons was not completed.

Specific Aim 2: The specific aim 2 was to explore the relationship between pain and comfort in the post-operative RALP patient. The null hypothesis: Decreased pain will not be associated with increased comfort.

A simple bivariate correlations was used. The correlations were computed at each time point and tested against the correlation of zero.

Determination of Sample Size

Power was first assessed for the repeated-measures ANOVAs. Simulations have been shown that HLM and repeated-measures ANOVAs have similar power pattern when same data were used (FANG, 2006). There will be two groups in the study:

Group A: Opioids

Group B: Opioids + α 2 agonist

There were two dependent variables for the ANOVAs (pain scale score, comfort score); each was evaluated on the interval scale of measurement. Therefore, the study employed two, repeated-measures ANOVAs, one ANOVA for each of the two dependent variables.

A priori power was estimated for the univariate repeated-measures ANOVAs. The analyses assumed that the sphericity requirement was met (Stevens, 2002; Tabachnick & Fidell, 2007). The analysis used a two-tailed alpha level set to .05. Overall power was set to .80, meaning the study will have an 80% probability of finding a significant difference if such a

difference exists in the population (Field, 2009; Wickens & Keppel, 2004). Equal sample sizes were assumed. The power analysis concentrated on the multivariate group-by-time interaction because it usually is the least powerful element in a repeated measures ANOVA (Field, 2009; Wickens & Keppel, 2004). A medium effect size was anticipated (Cohen's {1988} $f = .25$). Results showed an overall sample size of 38 would be required (19 subjects per group), assuming the correlation between the observation from the same subject is at least 0.2. This sample size was selected as the smallest sample that would be important to detect. Recruitment continued until both groups A & B of 23 per group were filled. This assumed a 15% attrition rate.

The study also calculated the bivariate association between pain and comfort scores for robotic laparoscopic prostatectomy patients. Therefore, a second power analysis was completed. Power for the bivariate analysis was set to .80. A large effect size was postulated (i.e., Cohen's {1988} $r = .50$). Results showed that an N of 26 would be required.

Given the discrepancy between the two power analyses, the more conservative sample size was employed. In other words, the sample employed 46 participants. This sample size was sufficient for both the repeated-measures ANOVAs and the bivariate-correlation analyses.

Data Collection

demographic data sheet.

The demographic data sheet was formed to gather additional information which may help to further explain results or improve understanding for this research study. There are many factors which may influence pain and comfort in the surgical patient population. These items were included as alternative possibilities toward impacting pain and comfort in addition to the set parameters of Group A and Group B. For example, hair color may play a role in sensitivity to pain and local analgesics as well as general anesthesia due to mutations of melanocortin-1

receptor gene which governs pigment formation and leads to red hair (Liem, Joiner, Tsueda & Sessler, 2005). In one study, red haired women required 19% more anesthetic than women with dark hair colors and redheads may be more sensitive to pain and more resistant to topical numbing medications than their darker hair counterparts (Liem, Joiner, Tsueda & Sessler, 2005).

The Demographic Data Sheet (DDS) contained 14 questions. A one-time completion of DDS was evaluated with an Estimated Time for DDS completion of less than five minutes. This questionnaire collected data documenting age, marital status, ethnicity, education level, socioeconomic status, race, history of chronic pain, daily pain medication list, cigarette smoking, exercise, hair color & how participant deals with pain and what alternate emotional/spiritual may have been used in the past to improve comfort and reduce pain. Participants were instructed not to answer anything they were uncomfortable with.

numeric pain rating scale.

Numeric Pain Rating Scale (NRS) asked the participant to rate intensity of their pain on a 0-10 scale. This self-report of pain describes pain in a numeric form on a graduated scale with 0 = No Pain and 10 = Severe pain or worst pain imaginable (NIH, 2003). Use of the Numeric Pain Rating Scale has been established as reliable and valid (Williamson & Hoggart, 2005). The NRS is frequently used in the postoperative period to evaluate pain. The Numeric Pain Rating Scale was evaluated four times in this study (pre-op, post-op upon PACU arrival, at PACU discharge, and upon arrival to medical/surgical unit). These measures were performed by registered nurses. Education was provided to all nurses regarding the Numeric Pain Rating Scale. The following script was used to rate pain: "On a scale of 0-10, 0 = No pain, 10 = Worst pain, please rate your pain. There is no right or wrong answer". Estimated time to completion Numeric Pain Rating Scale was less than one minute.

general comfort questionnaire (GCQ).

The General Comfort Questionnaire (GCQ) was used for this study. The GCQ considers a multidimensional personal experience with varying intensity degrees (Kolcaba, 1992). Subscales of physical, psychospiritual, environmental and social provide the construct of comfort (Kolcaba, 1992). The relationship of these subscales provides the grid for the taxonomic structure in a two dimensional format. The first dimension is intensity of met/unmet comfort needs with the second dimension being the degree of internal and external comfort needs (Kolcaba, 1992). The GCQ was generated from the taxonomic structure to measure this complex theory of comfort and has shown a statistically significant sensitivity in the area of comfort (Kolcaba, 1992). This questionnaire was completed using a likert scale ranging from strongly disagree to strongly agree. The higher the score the higher the total comfort.

The GCQ is a 28 item instrument using a 6 point likert scale ranging from 1 strongly disagree agree to 6 strongly agree (Kolcaba, 1992). Initial results for the original form of the Principal Components Analysis (PCA) showed all items measuring a single construct with a Cronbach's alpha = 0.88 (Kolcaba, 1992). Thirteen factors were extracted with eigenvalue > 1 (Kolcaba, 1992). Revised reliabilities increased Cronbach's alpha = 0.90 (Kolcaba, 1992). This instrument showed statistically significant sensitivity in the expected directions between several groups (Kolcaba, 1992). This questionnaire will be completed one time pre-op and one time post-operatively (medical-surgical unit). This questionnaire takes about 10-15 minutes to complete.

chart review for grouping & data analysis.

Medications used in the OR and PACU were recorded as well as participant age, height, weight, length of PACU stay and NRS score.

Protection of Human Subjects

This study was approved by the Fox Chase Cancer Center IRB with a Full Board Review. Further a letter of Reliance from Drexel University IRB and Fox Chase Cancer Center IRB was completed.

Research study participants were recruited at the physicians' offices or were recruited pre-operatively in the surgical department. In a confidential setting, individuals were asked if interested in participating in the study, and if so, consent was obtained. After informed consent, an identification number was assigned to each participant to ensure confidentiality, requesting all participants to place the assigned number on any paperwork that they completed. This information is stored in a locked file cabinet, accessed on by the PI. Only the PI has access to the research information. Data were transcribed to a secure computer and accessed only by the PI.

All data collection paperwork is kept in a locked & secure drawer in the Anesthesia CRNA Office with limited access only by the Primary PI. All electronic data are stored on a secured username & encrypted password computer and flash (USB drive) which was locked in the secured information drawer when not in use by the PI. Microsoft Office Excel & Microsoft Office Word documents were created for information gathering and data storage.

This study introduced minimal risk for subjects. Vulnerable populations such as age have been restricted in this study setting parameters at > 18 years of age since < 18 years of age are considered a vulnerable population. Informed consent clearly informed individuals of the studies nature provided the participants complete information about the study. Intent to ensure confidentiality was clearly explained within the informed consent document. Participants were given time to review the consent form as well as review written description of the purpose,

protocol, and risk/benefits of participating in the research study. Participants were provided time for discussion, and were provided the opportunity to ask questions prior to signing the consent form. The participants were asked to state the purpose and expectations of study prior to signing the consent form. The Principal Investigator (PI) or Sub-Investigator obtained written informed consent from the candidates who met the inclusion criteria for the study. Informed consent also included the discussion that research participation was voluntary and that they could withdraw from the study at any time. A copy of the signed informed consent form was given to the participant and a copy was kept by the principal investigator.

Chapter 4: Data Analysis and Results

A correlation analysis was conducted to determine the correlation between comfort and pain variables and repeated measures ANOVA were conducted to compare both comfort and pain levels according to time and group defining variables of whether the patient received opioid only or opioid and alpha 2 agonist pain medication post-operatively. The second repeated measures ANOVA (using the dependent variable of pain (NRS score) failed to demonstrate a normal distribution of the NRS scores by group and time, invalidating the use of the repeated measures ANOVA. Therefore, between group comparisons were made in relation to average post-operative pain, change in post-operative pain, and individual assessments of mean pain scores at the different time intervals.

Description of the Sample

The demographic data collected included the following, the level of education, marital status, race, and income, frequency of exercise, frequency of chronic pain and frequency of taking pain medications. The participants were divided into two groups: Group A, who received opioid medications, and Group B, who received a combination of opioid and alpha 2 agonist. Three of the Group A participants (opioids) and six of the Group B (opioids + alpha 2 agonist) participants did not complete all of the questions on the demographic form. The demographic data from the 19 participants from Group A and 18 participants from Group B are presented in Table 1. The demographic characteristics of the sample were analyzed for significant differences between the two groups (A and B) using a chi square analysis. These results are also presented in Table 1. None of the demographic variables demonstrate significant differences between groups, supporting that the groups are demographically similar.

Table 1

Demographic Characteristics of the Sample

Variable		Frequency			X^2	p
		Group A	Group B	*Total*		
Education Level	Grade School	1	1	2	1.435	.838
	High School Graduate	4	4	8		
	Some College	9	12	21		
	Undergraduate Degree	5	6	11		
	Graduate Degree	3	1	4		
Marital Status	Single	3	3	6	1.172	.760
	Married	16	19	35		
	Widowed	1	0	1		
	Divorced	2	2	4		
Income Level	<$10,000	0	1	1	3.719	.715
	<$20,000	2	2	4		
	<$25,000	1	0	1		
	<$50,000	4	4	8		
	<$75,000	4	2	6		
	<$100,000	1	3	4		
	>$100,000	7	6	13		
Race	Caucasian/White	17	17	34	.069	.793
	Black/African American	5	6	11		
Chronic Pain	No/Never	18	12	30	7.728	.102
	Rarely	2	8	10		
	Occasionally	1	3	4		
	Yes, Sometimes	0	1	1		
	Always	1	0	1		
Pain Meds	Never	9	5	14	2.394	.495
	Rarely	10	14	24		
	Occasionally	2	4	6		
	Weekly	0	0	0		
	Daily	1	1	2		
Exercise codes	Never	2	2	4	2.293	.514
	Rarely	6	4	10		
	Occasionally	10	9	19		
	Regularly	4	9	13		
Hair Color	Black	6	5	11	2.394	.664
	Blonde	1	1	2		
	Brunette	10	9	19		
	Red/Auburn	0	2	2		
	Other	5	7	12		

Smoking History	Daily	0	2	2	2.985	.394
	Never	14	14	28		
	Occasionally	1	0	1		
	Quit Smoking	7	8	15		

In addition to the demographic data listed in Table 1, additional data were collected to determine the average age, height, weight, and BMI of the participants. These data are presented in Table 2, with the mean (M), standard deviation (SD), and standard error (SE) given for each group (A and B). The results included data from 22 participants from Group A and 24 participants from Group B. Table 2 also presents the results of an independent sample t-test to determine if these variables differ significantly according to group. With the exception of the age variable, equal variances between the two groups could not be assumed and therefore, non-pooled data were used to complete the independent samples t-test analysis. T-test results aligned with those from Table 1, supporting similarity of the sample with regard to age, height, weight, and BMI.

Table 2

Demographic Variables of Age, Height, Weight, and BMI

Variable	Group	N	M	SD	SE	t	p
Age	Group A	22	60.77	8.54	1.85	1.684	.099
	Group B	24	57.08	6.23	1.27		
Height	Group A	22	70.77	1.90	.405	1.826	.075
	Group B	24	69.52	2.71	.553		
Weight	Group A	22	89.89	9.60	2.05	-.691	.494
	Group B	24	92.63	16.61	3.39		
BMI	Group A	22	27.86	3.08	.657	-1.537	.132
	Group B	24	30.50	4.74	.968		

Correlations

To begin the data analysis, Pearson correlation was calculated between the comfort (GCQ) variable and the pain (NRS) variable at each time measure (see Table 3). The study incorporated two repeated measures for the GCQ data and four time measures for the NRS data. Correlation results failed to demonstrate any significant correlation between pain and comfort level in the patient sample.

Table 3

Correlations

		NRS time1	NRS time2	NRS time3	NRS time4
GCQ time1	Pearson Correlation	.122	-.116	.151	-.010
	Sig. (2-tailed)	.418	.442	.317	.947
	N	46	46	46	46
GCQ time2	Pearson Correlation	-.004	-.090	-.095	.171
	Sig. (2-tailed)	.979	.549	.526	.249
	N	47	47	47	47

General Comfort Questionnaire (GCQ)

The second part of the data analysis was the examination of the repeated measures related to the comfort (GCQ) scores. Descriptive statistics of the GCQ scores over time and according to group are given in Table 4.

Table 4

Descriptive Statistics for GCQ Score by Time and Group

	Group	Mean	Std. Deviation	N
GCQ time1	Group A Opioids	88.60	12.348	20
	Group B Opioids + alpha 2 agonist	81.46	11.356	24
	Total	84.70	12.218	44
GCQ time2	Group A Opioids	92.90	10.427	20
	Group B Opioids + alpha 2 agonist	89.75	11.906	24
	Total	91.18	11.242	44

Graphing these mean scores over time, the higher pain score trend of Group A was visualized (see Figure 2).

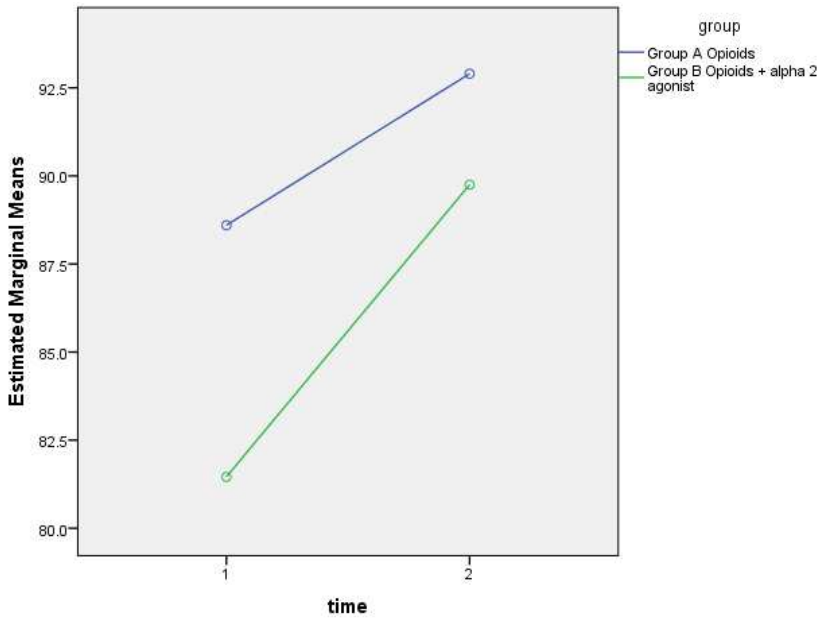

Figure 1. Estimated Marginal Means of GCQ scores

To test for significance of differences in GCQ scores by time interval and by whether or not the alpha 2 agonist was added to the pain medication protocol (Group A versus Group B), assumptions were checked for the use of the repeated measures ANOVA. Visualization of the Q-Q plot for each group at each time interval revealed a relatively normal distribution of the data (Figure 3). This was checked using the Shapiro-Wilk test of normality, which supported that the data met the assumption of approximate normal distribution (Table 5). Because there were only two time intervals, Mauchly's test was not used to check spheracity, but rather, Levene's test was used to evaluate the equality of the error variances of the dependent variable, which supported the equal variance assumptions ($p > .05$) (Table 6). Therefore, the use of the repeated measures ANOVA was validated.

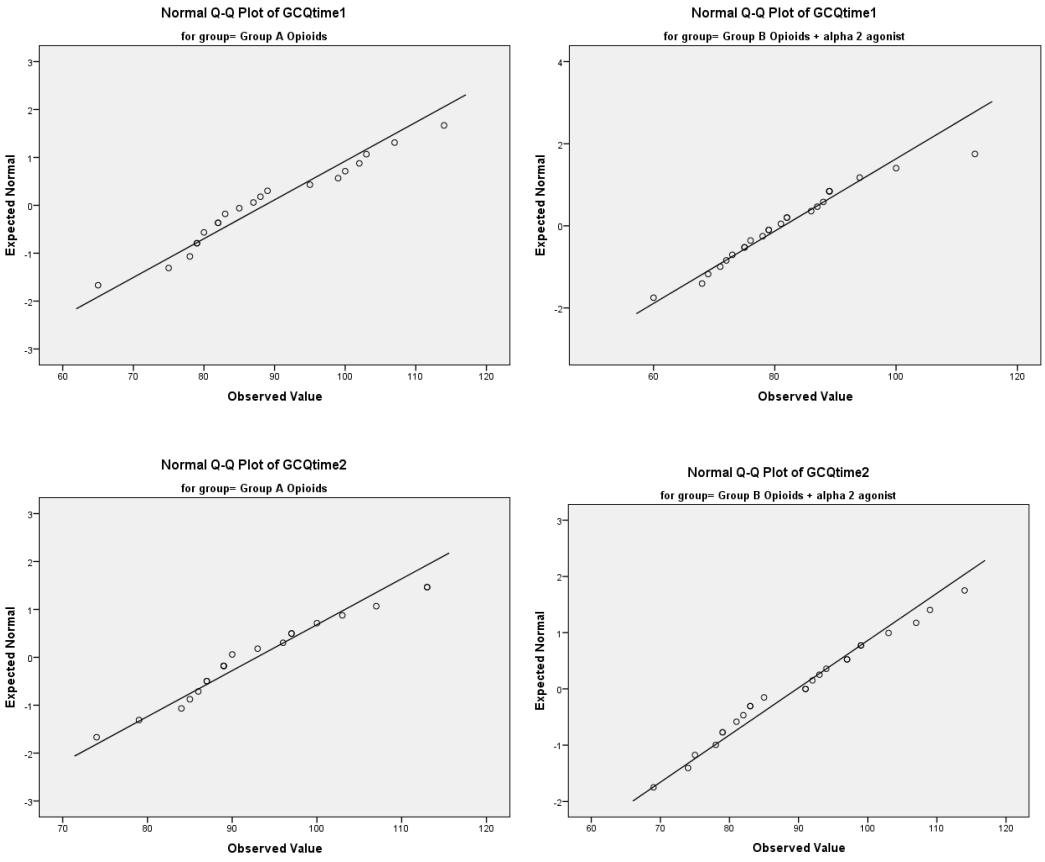

Figure 2. Q-Q Plot distributions of GCQ scores by time and group

Table 5

Shapiro-Wilk Tests of Normality for GCQ Data by Time and Group

		Shapiro-Wilk		
	Group	Statistic	df	Sig.
GCQ time1	Group A Opioids	.963	20	.601
	Group B Opioids + alpha 2 agonist	.960	24	.444
GCQ time2	Group A Opioids	.955	20	.455
	Group B Opioids + alpha 2 agonist	.973	24	.753

Table 6

Levene's Test of Equality of Error Variances for GCQ Data

	F	df1	df2	Sig.
GCQ time1	.455	1	42	.504
GCQ time2	.786	1	42	.380

Having met the assumptions for use, the repeated measures ANOVA was conducted on the GCQ mean scores (comfort scores) by time (repeated measure) and group. From Table 7, the F value for the "time" factor is significant ($p < .001$). Thus, using the ANOVA for repeated measures, the mean scores for GCQ were found to be significantly different over the two time intervals. However, the interaction of the time scores with group failed to demonstrate significance. Therefore, although over time the GCQ scores were significantly different, this difference was not related to group (i.e., not related to whether the patient had the addition of the alpha 2 agonist for pain management). Despite the significant effect of time, no interaction with the experimental variable defining the two groups (opioids vs opioids + alpha 2 agonist) was evident.

Table 7

Tests of Within-Subjects Contrasts

Measure: GCQ Source	time	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
time	Linear	864.819	1	864.819	17.662	.000	.296
time * group	Linear	86.909	1	86.909	1.775	.190	.041
Error(time)	Linear	2056.579	42	48.966			

Table 8

Tests of Between-Subjects Effects Measuring GCQ by Time and Group

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Intercept	678562.737	1	678562.737	3120.690	.000	.987
group	577.737	1	577.737	2.657	.111	.059
Error	9132.479	42	217.440			

The conclusion of the repeated measures ANOVA for the post-operative GCQ (comfort) scores demonstrated a significant effect related to time (time of measure), the results failed to demonstrate any between group differences in comfort (GCQ) over time based on whether or not the patient received opioid only or opioid and alpha 2 agonist post-operative pain medication.

Numeric Pain Rating Scale (NRS)

In a similar effort to evaluate changes in reported pre and post-operative pain level among the patient sample, the mean NRS pain score data were evaluated using descriptive statistics for each of the four time interval measures (Table 9).

Table 9

Descriptive Statistics for Pain (NRS)

	Group	Mean	Std. Deviation	N
NRStime1	Group A Opioids	.73	1.907	22
	Group B Opioids + alpha 2 agonist	.04	.204	24
	Total	.37	1.356	46
NRStime2	Group A Opioids	1.50	2.596	22
	Group B Opioids + alpha 2 agonist	1.08	2.283	24
	Total	1.28	2.419	46
NRStime3	Group A Opioids	2.41	2.955	22
	Group B Opioids + alpha 2 agonist	.92	1.767	24
	Total	1.63	2.498	46
NRStime4	Group A Opioids	2.77	2.069	22
	Group B Opioids + alpha 2 agonist	2.83	2.761	24
	Total	2.80	2.428	46

Graphing these data points, the higher pain score trend of Group A was visualized, along with the similar fourth time measure NRS scores (see Figure 4).

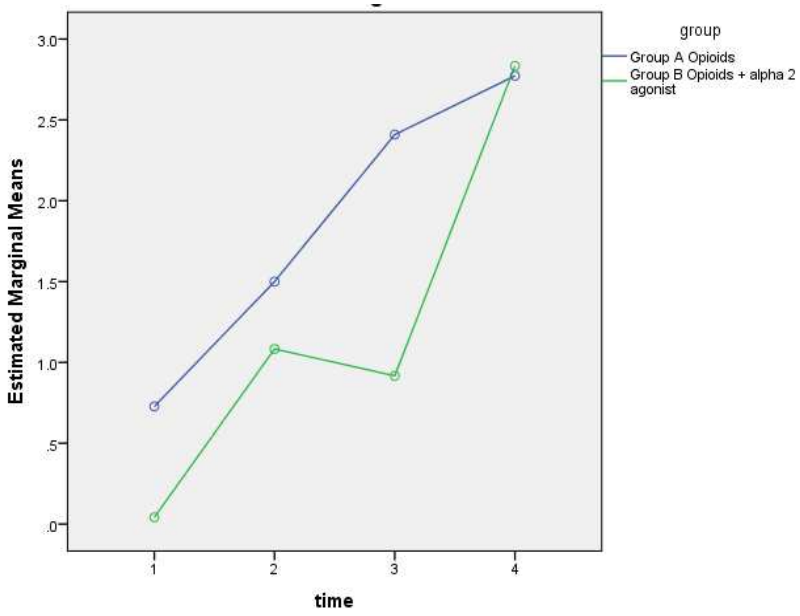

Figure 3. Estimated Marginal Means of NRS (pain) scores

To test for significance of these differences in NRS scores by time interval and by whether or not the alpha 2 agonist was added to the pain medication procedures (Group A versus Group B), assumptions were checked for the use of the repeated measures ANOVA through generation of Q-Q plots, histograms, the Shapiro-Wilk test, and Mauchly's test for spheracity, according to group and time interval, with repeated measures collected at four time intervals (pre-operative, post-operative at the PACU arrival, post-operative at PACU discharge, and post-operative at arrival to the medical/surgical unit).

Although the data upheld the assumption of spheracity with a Mauchly's Test significance of $p = .098$, because the data failed to demonstrate a normal distribution across the different time measures and groups (use of Q-Q plots and Shapiro-Wilk test, $p < .05$ for all groups in the different time intervals (with the exception of time 4, in which $p = .118$), the results of the repeated measures ANOVA were not valid.

Table 10

Shapiro-Wilk Test of Normality for NRS by Time and Group (Pain)

		Shapiro-Wilk		
	group	Statistic	df	Sig.
NRStime1	Group A Opioids	.423	22	.000
	Group B Opioids + alpha 2 agonist	.209	24	.000
NRStime2	Group A Opioids	.643	22	.000
	Group B Opioids + alpha 2 agonist	.539	24	.000
NRStime3	Group A Opioids	.802	22	.001
	Group B Opioids + alpha 2 agonist	.589	24	.000
NRStime4	Group A Opioids	.929	22	.118
	Group B Opioids + alpha 2 agonist	.876	24	.007

In an effort to understand the differences on graphic illustration between groups in terms of mean NRS scores at the different time measures (Figure 4), a change in pain score (NRS score) was calculated from the pre-operative (time 1) to the final post-operative (time 4) interval. The difference was then compared across the two groups.

Although the Shapiro-Wilk tests were significant (suggesting non-normal distribution) (see Table 11), given the robustness of the test and upon visualization of the Q-Q Plots and histograms (Figure 5), the data were deemed approximately normally distributed to allow for an examination using an independent sample t-test to evaluate between group differences in the change of NRS score from pre-operative to final post-operative data collection. In addition, the Levene statistic was found nonsignificant, indicating that equal variances could be assumed ($p = .295$).

Table 11 next page

Table 11

Shapiro-Wilk's Test of Normality for Change in NRS Score by Group

		Shapiro-Wilk		
	group	Statistic	df	Sig.
Change in NRS score	Group A Opioids	.893	22	.022
	Group B Opioids + alpha 2 agonist	.906	24	.029

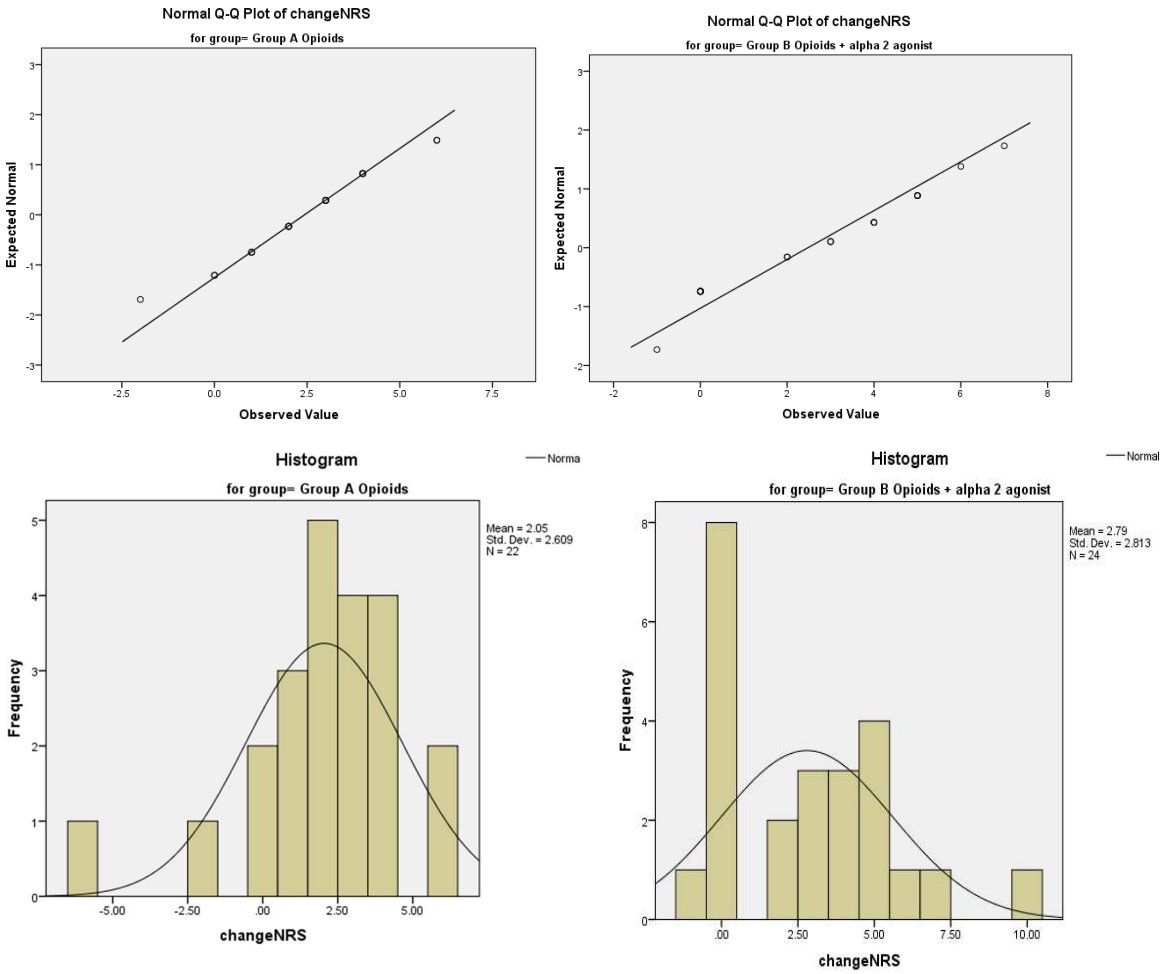

Figure 4. Q-Q Plot and Histograms for Group A and Group B for analysis of normality for the calculated variable of Change in NRS pain score (preoperative to postoperative).

Results from the analysis suggest that although the descriptive statistics revealed a greater change in pain score among Group B participants compared to Group A participants (Table 12), this difference was not statistically significant using the independent samples t-test (p = .357) (Table 13).

Table 12

Group Statistics for Overall Change in NRS Mean Scores

	Group	N	Mean	Std. Deviation	Std. Error Mean
Change in NRS score	Group A Opioids	22	2.0455	2.60909	.55626
	Group B Opioids + alpha 2 agonist	24	2.7917	2.81269	.57414

Table 13

Independent Sample t-Test for Overall Change in NRs Score (pre to post-operative)

	t-test for Equality of Means						
						95% CI of the Difference	
	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Change in NRS score	-.930	44	.357	-.74621	.80208	-2.36270	.87028

However, because of the questionable non-normal distribution of the data, this result was checked against the nonparametric alternative to the independent samples t-test, the Mann-Whitney U test. The results of the Mann-Whitney supported the results obtained by the t-test, which failed to reject the null hypothesis (p =.625), indicating no significant difference across groups in terms of the overall change in pain level (NRS score). A similar analysis of a calculated variable of the average total post-operative pain (NSR) score (the sum of times 2, 3, and 4, divided by 3) was conducted, again using the nonparametric Mann-Whitney U test, supporting the conclusion that no between group differences were evident in the mean total post-operative pain scores (p = .319)

Seeking to understand the lack of significance between group differences, the researcher also examined the mean NRS scores at the individual time measures independently. Descriptive statistics (Table 14) demonstrated higher pain scores for Group A (Opioids only) in the first three time measures and roughly equal mean NRS scores in the fourth time measure, aligning with the estimated marginal means graph presented earlier (Figure 4).

Table 14

Descriptive Statistics for NRS Variable by Time and Group

	group	N	Mean	Std. Deviation	Std. Error Mean
NRStime1	Group A Opioids	22	.73	1.907	.407
	Group B Opioids + alpha 2 agonist	24	.04	.204	.042
NRStime2	Group A Opioids	22	1.50	2.596	.553
	Group B Opioids + alpha 2 agonist	24	1.08	2.283	.466
NRStime3	Group A Opioids	22	2.41	2.955	.630
	Group B Opioids + alpha 2 agonist	24	.92	1.767	.361
NRStime4	Group A Opioids	22	2.77	2.069	.441
	Group B Opioids + alpha 2 agonist	24	2.83	2.761	.564

To examine these differences at each individual time interval separately for significance, the assumptions were checked to validate the use of an independent samples t-test. Q-Q plot visualization failed to show normal distribution of the data in any of the four time periods and Shapiro-Wilk tests were nearly all significant (see Table 15), indicating a violation of the assumption of normal distribution for the data across the sample groups.

Table 15 next page

Table 15

Tests of Normality

		Shapiro-Wilk		
	group	Statistic	df	Sig.
NRS time1	Group A Opioids	.423	22	.000
	Group B Opioids + alpha 2 agonist	.209	24	.000
NRS time2	Group A Opioids	.643	22	.000
	Group B Opioids + alpha 2 agonist	.539	24	.000
NRS time3	Group A Opioids	.802	22	.001
	Group B Opioids + alpha 2 agonist	.589	24	.000
NRS time4	Group A Opioids	.929	22	.118
	Group B Opioids + alpha 2 agonist	.876	24	.007

Therefore, non-parametric alternative to the independent samples t-test, the Mann-Whitney U test, was conducted to examine the data for differences in mean NRS scores across the two groups at each individual time measure. Results are given in Table 16. The only significant difference between groups was in the mean scores during the third time measure (post-operative, as PACU discharge) with the "opioids only" group (group A) demonstrating a significantly higher pain score compared to the group B sample of opioids + alpha 2 agonist ($p < .05$). This result aligned with the visualized changes in the estimated marginal means graph presented earlier (Figure 7). The lack of significant between group differences at the other individual time measures (times 1, 2, and 4) likely contributed to the lack of significant between group differences across the repeated measure.

Table 16

Mann-Whitney U Test Results of NRS Mean Scores at Different Times

Distribution of NRS mean scores	Mann-Whitney U Test p-value
Time 1	.233
Time 2	.442
Time 3	.050
Time 4	.920

Conclusion

In general, the study results failed to demonstrate any between group differences in pain (NRS score) or comfort (GCQ) over time based on whether or not the patient received opioid only or opioid and alpha 2 agonist pain medication. Time was found to have a significant effect on GCQ (comfort variable), but no interaction with group was noted, suggesting no group differences in comfort level. The only significant difference in pain level (NRS) was found at the time 3 measurement (post-operative at PACU discharge, at which time the Group A (Opioids only) demonstrated a significantly greater pain score compared to the Group B patients (Opioids and alpha 2 agonist). In addition, no correlation was evident between comfort (GCQ) and pain (NRS) variables. The study results were limited by the frequent non-normal distribution of the data and the relatively small group sample sizes. A larger sample size may contribute to enhanced results and understanding of the interactions of pain and comfort in the post-operative period in relation to pain management methods.

Chapter 5: Summary of Dissertation Research

Overview

Patients undergoing a robotic assisted laparoscopic prostatectomy are quickly moving through the hospital system postoperatively toward discharge on postoperative day one through day four with a mean hospitalization of 1.6 days in the United States (Humphreys, Gettman, Chow, Zincke, Blute, 2004). The minimally invasive robotic assisted procedure compared to open incision have had conflicting reports to determine if there is less pain with five small port incisions compared to one larger incision and if this affects the patients recovery and convalescence (Humphreys, Gettman, Chow, Zincke, Blute, 2004). The effectiveness of our pain and comfort strategies will guide our practice toward the best pain management strategy for this robotic laparoscopic procedure.

Pain management is an issue which needs to be addressed with the current advances in surgical technology (Carr, Reines, Schaffer, Polomano, Lande, 2005). Laparoscopic minimally invasive procedures have improved patient outcomes with a decrease in blood loss, a reduction in overall pain and a shortened hospitalization (Humphreys, Gettman, Chow, Zincke, Blute, 2004).

Pain and comfort are subjective to an individual's experience and measuring and treating these parameters is an important part of the surgical experience. The importance of pain and comfort measurement and treatment, may help guide care in the surgical patient. The Joint Commission has identified a patient right to receive effective pain and comfort management and institutional regulations have been designed to ensure this goal (Krenzischek & Wilson, 2003). To meet TJC regulations, the Agency for Healthcare, Research & Quality (AHRQ) also

emphasizes that safe pain management needs to be provided by institutions (Krenzischek & Wilson, 2003). The American Society of Perianesthesia Nurses (ASPAN) has developed a Pain and Comfort Clinical Guideline to assist with the Joint Commission regulation for all individuals to have the right to effective pain/symptom management (ASPAN, 2015; Krenzischek & Wilson, 2003). This guideline begins with assessment of pain (0-10 scale) and continues with assessment of medical, pain and comfort history in addition to analgesic history, educational and cultural needs (Krenzischek & Wilson, 2003). Interventions and post anesthesia interventions are presented in the guideline along with expected outcomes (Krenzischek & Wilson, 2003).

The Institute of Medicine (IOM) has developed an initiative not only to assess and treat pain, but to make it a significant part of the American culture through improved awareness about prevention, health implications, assessment and management in healthcare and patient education (IOM, 2011). Further focus for the IOM's initiative is to finance programs, address disparities, reduce knowledge gaps in healthcare and the general population, and improve research (IOM, 2011). Measurements of comfort and pain management were used for this research. The Numeric Pain Rating Scale were used in this research to assess pain and determine analgesia effectiveness. The General Comfort Questionnaire was used to measure comfort after RALP procedure was performed. Determination of the pharmacological doses required for best pain and comfort were determined using two groups (opioids & opioids plus alpha 2 agonist). These measures were important to guide effectiveness of medications used according to participant's pain and comfort perception. Using a variety of analgesics may assist in minimizing unwanted opioid effects such as sedation, respiratory depression, nausea & vomiting along with reduced opioid consumption. Pain management was measured prior to surgery to document a baseline rating, and also measured on arrival to PACU, before discharge from PACU and upon arrival to

the medical/surgical room. These time measurement intervals enabled the researcher to examine and re-examine the pain rating. Pain management criteria need to be developed to maintain control of pain and allow for expeditious discharge from the hospital after surgery (Michaloliakou, Chung, Sharma, 1996). Nursing personnel need to be aware of the potential side effects and complications of surgical procedures and the pain management medications (Michaloliakou, Chung, Sharma, 1996). Research needs to be done to determine the best combination of pain medication with the least possible side effects to keep the patient comfortable and safe (Michaloliakou, Chung, Sharma, 1996). The nursing profession needs to realize their accountability for pain and comfort management and continue to improve pain and comfort management techniques (White, 2005).

Authors Summary of Findings

The importance of pain and comfort has been described throughout this document and is an area of significant focus for many stakeholders including but not limited to, The Joint Commission, consumers and their regulating bodies, The Veterans Administration, Nursing, the Agency for Healthcare, Research & Quality and the Institute of Medicine (Department of Veteran Affairs, 2000; TJC, 2000; Jha, Orav, Zheng & Epstein, 2008).

There were no significant differences in group characteristics between the opioids alone and opioids plus alpha 2 agonist, such as age, weight, exercise, and other variables collected on the Demographic Data Form. The average age of the participant was between 57-60 years old with some college education and married. The mean height and weight were approximately 70 inches and 90 kg respectively. The average participant did not experience chronic pain, took pain medications rarely, had brunette hair, was a non-smoker and occasionally exercised.

In summary, no differences were found between groups A and B in pain (NRS score) or comfort (GCQ score) over time. Time was found to have a significant effect on GCQ (comfort variable), but no interaction with group was noted, suggesting no group differences in comfort level. The only significant difference in pain level (NRS) was found at the time 3 measurement (post-operative) at PACU discharge, at which time opioid only group demonstrated a significantly greater pain score compared to opioid plus alpha 2 agonist participants. Furthermore, there was no correlation between comfort and pain. This research was limited due to the relatively small group sample sizes. A larger sample size may result in different findings.

One significant finding in this study was an increase in NRS (pain score) during PACU discharge (time 3) in opioid only group with a lower pain score in the opioid plus alpha 2 agonist group. This result supports the use of multi-modal analgesia. Another difference was found in the GCQ (comfort) time from the first assessment to the second; however, there were no differences found between the specific groups' opioid alone and opioid plus alpha 2 agonist. Maybe a larger study group could impact the variation in time for the comfort score (GCQ).

This study examined a combination of modern modalities and intravenous agents focusing on robotic prostate surgery and the use of alpha 2 agonists with and without opioids for improved patient pain and comfort management. The alpha 2 agonist (dexmedetomidine) is a medication which has potential to reduce total opioid requirements and reduce pain. A recent study from researchers at Geneva University Hospital in Switzerland provides evidence of decreased opioid use in surgical patients with use of alpha 2 agonists (AANA, 2012). Additionally, the patients in this study had slightly less pain after their surgery (AANA, 2012). It is possible that no differences were noted in this study because pain was adequately controlled in both groups. Pain scores were noted to be higher in group A for Time 1, 2 and 3, however a

significance between groups was not found. Although the results of this study did not have an overall significant difference between the Opioid group & Opioid and alpha 2 agonist group, there was some significance noted with the pain score just prior to PACU discharge between those participants who received the alpha 2 agonist and those who did not. The only significant difference in pain level (NRS) was found at the time 3 measurement (post-operative at PACU discharge), at which time the opioid group demonstrated a significantly greater pain score compared to the opioids and alpha 2 agonist group.

The use of multi-modal therapy in anesthesia has been shown to reduce total dose of opioids; thereby reducing adverse side effects of these potent medications (Blaudszun, Lysakowski, Elia &Trame` r, 2012; AANA, 2012). The Geneva University study gathered information from 30 different studies which included 1792 patients, 933 of them received an alpha 2 agonist revealing a 25-30% reduction in administered opioids and a lower postoperative pain score. Further, typical adverse effects of opioid medications were reduced with participants receiving the alpha 2 agonists (AANA, 2012; Blaudszun, Lysakowski, Elia & Trame`r, 2012).

Improving our understanding of the benefits of the use of alpha 2 agonists is imperative to continue forward movement with modern surgical interventions such as robotic surgery. Although there are many benefits to the use of alpha 2 agonists, precautions must be taken during administration. Concerns with administration of these agents are secondary to significant fluctuations in hemodynamic stability with an overall reduction in blood pressure and heart rate (Blaudszun, Lysakowski, Elia, Trame`r, 2012). Therefore, the use of these agents should be

restricted to authorized personnel and monitoring and trained personnel are required during administration.

Significance to Nursing Practice

White & Kehlet (2010) suggest routine implementation of procedure specific evidence based pain management protocols to improve perioperative pain control. This study's aim was to find the best combined pharmacologic therapy to improve patient comfort, minimize pain, and safely facilitate an expedient discharge to home. With the significant growth of robotic surgery throughout the United States, it is essential to implement the best pain strategy available (Cleary & Nguyen, 2002).

Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) data has shown a high correlation between patient satisfaction with hospital care, nursing communication, and adequate pain control (Cronbach's alpha of 0.84) (Jha, Orav, Zheng & Epstein, 2008). More recent surveys have demonstrated insufficient pain management in the post-operative setting (White & Kehlet, 2010). Clinical performance data released publically has prompted improvements in quality of care which may lead to improvements in patient centered care (Jha, et al., 2008). Further, improvements in hospital quality of clinical care have been prompted due to public release of HCAHPS data (Jha, et al., 2008).

Robotic procedures assist in expediting hospital discharge however, patient preparedness for home care rests in the balance. Pain and comfort are important factors to consider in our daily nursing practice. Our goal to minimize pain, improve comfort and maintain safety is a continued balance in the times of rapid hospital discharge and minimally invasive surgery. As our understanding of patients' needs increases, and as continued research is completed we strive to continue improving this fine balance of pain, comfort and safety.

This study did not reveal a benefit to nursing practice at this time, however; if a larger population were to be studied the findings might be different.

Limitations of the Study

A variety of factors may have influenced the results of this research study including small sample size, ethnic and racial diversity, questionnaire administration (subjective), pharmaceutical agent selection and dosing, and lack of a control group. Non pharmacological interventions as adjuvant pain and comfort control (acupuncture, relaxation, music, hypnosis, transcutaneous nerve stimulation) were not used in this research. Alternative non pharmacological interventions could also contribute to reduction of pain.

The sample size was set for an 80% probability of finding a significant difference if a difference did exist in this population. With the calculated medium effect size and 15% attrition anticipation, the estimated number of each group was 23 participants to meet the minimum requirement for this effect and probability. This study had a small sample size but it was appropriate for a pilot study.

A limitation in this research design was the lack of a control group with set dosing of opioids and alpha 2 agonist. Another limitation of this study was no control for dose or time of medication administration. Specific doses at given times may reveal a more sensitive reflection of pharmacologic effect and improved comparison with the opioid alone Group A. Further, comparison of larger and smaller doses could be valuable to provide information for increased or decreased opioid quantities required.

The research setting provided a limited population sample secondary to the hospital's limited ethnic and racial diversity of participants. Further analysis requirements for

generalization of findings are not possible with the small sample size and limitations of this study.

The General Comfort Questionnaire was completed by each participant as a self-report as opposed to a direct observational/questionnaire. Personal interview for the General Comfort Questionnaire may possibly improve the participants' response toward a positive or higher value. Although the GCQ was formulated for each participant to self-assess, an improved response in a positive direction may have occurred secondary to each participant receiving the questions in the same manner, tone, with the ability to answer questions.

Recommendations for Future Research

The results of this research study demonstrated the positive finding in the NRS reduced pain score in Group B during time 3 which warrants further research. Further, results may be improved with set dosing at a higher and lower ranges and at specific time intervals. This finding provides information which further warrants future research pertaining to pain control and comfort with the use of alpha 2 agonists in the anesthesia and PACU settings.

Analgesia is an important part of pain and comfort management for all patients, but especially for the postoperative patient who is on the fast track for discharge. Factors which play a significant role in our choices for pain and comfort management of these patients are the rapid discharge from the hospital, side effects of individual analgesics, specifically opioids, and the need for patients to continue their activities of daily living without interference from sedation. Taking all of this into account, our current plan can use improvement. According to literature patients are still discharged to home without adequate pain control. Healthcare providers must take into account and be educated in pain and comfort management of the postoperative patient in order to best facilitate comfort and a safe discharge from the hospital setting to home.

A larger sample of participants with larger variation of diversity may improve findings. A recommendation for future research in a larger facility with multiple settings and a wider range of ethnicities and races could improve applicability to the general population. Further participant assistance with questionnaire completion could improve the process of data collection and outcomes.

Patient comfort and reduced pain play a critical role in improving health care for each and every individual. Continuing to search for the best pharmacologic therapeutic regimen for minimally invasive procedures, such as robotic assisted laparoscopic prostatectomy is an important research subject in order to improve pain and comfort for these patients.

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Appendix A

"Pain is whatever the experiencing person says it is, existing whenever the experiencing person says it does" McCafferty & Beebe.

What Happens During This Study?

The Study will be thoroughly explained to you and you will be given the opportunity to ask questions. After you have an understanding of the study, you will be asked to sign a consent form.

You may choose to withdraw from the study at any time, for any reason. This is a completely voluntary study, your care will not be affected whether you choose to participate in this study or not.

You will be asked to complete a general information sheet before your surgery one time only. This takes less than 5 minutes to complete.

You will be asked to rate your pain a total of four times (before surgery, immediately after surgery, before leaving the recovery room and upon arrival to your room. This is done routinely and takes less than 1 minute.

You will be asked to fill out a Questionnaire about your Comfort a total of two times. Before your surgery and after you arrive in your room following your surgery. This questionnaire takes about 5-10 minutes to complete.

This study will not affect the care you receive. After your surgery & recovery, your chart will be reviewed. This information will be evaluated along with your questionnaires & pain rating information.

What are the Risks?

This is an Observational Study which means there is no study drug or procedure being tested. Questionnaires will be given and medical records will be reviewed.

Will my Safety Be Protected?

Clinical Research Studies are very closely controlled and require approval by an Institutional Review Board. This independent group has both medical experts and an individual from the community to safeguard individuals through assessment of risks.

When Does the Study End?

After the final questionnaire is complete your medical record will be reviewed to gather information concerning your pain & comfort surrounding your robotic surgery. Once all groups are complete, participants' medical information will be analyzed to determine whether pain & comfort were higher in one group over another. This will complete the Study.

Fox Chase Cancer Center

333 Cottman Avenue
Philadelphia, PA 19111
Call **1-888-FOX-CHASE**
(1-888-369-2427)

Appendix A (continued)

CLINICAL RESEARCH AT FOX CHASE CANCER CENTER

IMPROVING OUR UNDERSTANTDING OF PAIN CONTROL & COMFORT AFTER A ROBOTIC SURGICAL PROCEDURE

Kimberly A. Davis, DrNP(c), CRNA

Primary Investigator

Pager (215) 308 1262

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BROCHURE FRONT

Appendix A (continued)

EVALUATING YOUR PAIN CONTROL & COMFORT

Fox Chase Cancer Center Mission
To prevail over cancer, marshaling heart and mind in bold scientific discovery, pioneering prevention, and compassionate care.

1. Your pain control and comfort are important factors in healthcare.

2. By taking a few moments to complete questions about your pain and comfort during your care you will be helping to improve our understanding of needs for pain medicine during robotic surgery.

3. Identifying the relationship of pain management to comfort in this robotic surgical procedure through comparison of two standards of anesthesia care will help to determine the best pain management strategy.

4. Optimizing pain control and comfort levels are key issues important in promoting a rapid recovery and discharge from the hospital.

5. This study will provide a scientific base for development of improved pharmacologic pain and comfort interventions. Pain and comfort in this relatively new procedure has not been adequately addressed. This study will provide important information about the efficacy of pain after surgery by comparing two anesthetic groups. The results could be used to guide future anesthetic practice.

What is a Clinical Research Study?

A Clinical Research Study is an investigation which helps caregivers discover new and improved ways to treat disease and improve healthcare. Research helps advance new treatment options, where smaller groups will be tested for safe and effective advancements in care.

Why would you agree to take part in a Clinical Research Study?

Choosing to take part in a Clinical research Study allows you to help others through contributing to medical research. Although you may not receive any direct benefit from your participation, future advancements for treatment and care may be a result of your participation.

Who can Participate?

Screening is routine to see if you are interested and that you meet the requirements of the study. Guidelines for each study describe who may be included or excluded depending on what the study needs are.

What is a Protocol?

A Protocol explains in detail exactly what is being studied and all of the procedures to be followed during that study.

Appendix A (continued)

YOUR PAIN CONTROL & COMFORT IS IMPORTANT TO US

Comfort is defined as… "The immediate state of being strengthened by having the human needs for relief, ease, and transcendence (types of comfort) addressed physically, psychospiritually, socioculturally, and environmentally" Wilson & Kolcaba

By Participating in this Study, You Can Help Improve Pain Control & Comfort Care

BROCHURE BACK

Appendix B

FOX CHASE
CANCER CENTER

INFORMED CONSENT DOCUMENT

Pain Management and Comfort in Robotic Laparoscopic Prostatectomy Patients

Principal Investigator: Kimberly A. Davis, DrNP(c) CRNA

This is a clinical trial, a type of research study. Your study nurse will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You should discuss your decision with your friends and family. You will also discuss it with your health care team. If you have any questions, you can ask your study nurse for more explanation.

You are being asked to take part in this research study because you have Prostate Cancer and have chosen Robotic Laparoscopic Prostatectomy surgery.

The sponsor of this study is **Fox Chase Cancer Center.**

Why is this research study being done?

The purpose of this study is to find out the best pain management strategy after your procedure. We would like to find out what combination of medications work best after your surgery. You will receive the same care and medications chosen by your anesthesia provider whether or not you participate in this study. These medications will be reviewed after your surgery is complete and compared to your pain score. We do not know if you will benefit from this research study. We can use what we learn from this research study to help other people with the same disease.

How many people will take part in this research study?

About 23 people for each group (two groups) will be needed for this research. A total of 46 people will take part in this research study if able to fill groups evenly.

What will happen if you take part in this research study?

Before you begin the research study... You will be given a Demographic Data Sheet to complete. Prior to surgery, The Numerical Rating Scale (NRS) and Comfort Questionnaire will be completed. Postoperatively, upon arrival to the Recovery Room (Post Anesthesia Care Unit PACU) and at PACU discharge, the NRS will be administered. The Numerical Rating Scale will be completed in the recovery area by the PACU RN. Upon PACU discharge to medical/surgical room, the Numerical Rating Scale and Comfort Questionnaire will be completed. Evaluation of medical record will provide medications received intraoperatively.

Appendix B (continued)

This will place participant in Group A or B. Further medications will be recorded from PACU setting.

No tests or procedures will be required to participate in this study.

During the research study...

If you choose to take part in this research study, then you will be asked to participate in answering the Comfort Questionnaire information. The Numerical Rating Scale and medications provided during your care are part of regular cancer treatment.

- ***Comfort Questionnaire***

You will receive the Numerical Rating Scale as a part of regular cancer care. This is being done no different because you are in this research study.

- ***Numerical Rating Scale***

You will need no tests or procedures for this research study. Your chart will be reviewed after your surgery to determine what medications you received and review your Numerical Rating Scale Scores.

- ***Medication Review for group placement***

Questionnaires

We are asking you to fill out a Demographic Data Form which is a Questionnaire that will be filled out one time only and takes < 5 minutes for completion.

We are asking you to fill out questionnaires about comfort for this research study. This questionnaire will tell us about your pain and your comfort. You will spend 10-15 minutes to fill out the comfort questionnaire. We will ask you to fill this out before your surgery one time and one time after your surgery to total two times during this research study.

You do not have to answer any questions that make you uneasy. Whether or not you answer any question will not affect your medical care. We will keep the paper copies of the questionnaires in a locked file to protect your privacy.

Appendix B (continued)

Study Chart

You will receive **a questionnaire** one time before your surgery and one time after your surgery describing your comfort for this research study. This [two questionnaires from before your surgery until you return to your room] is called a cycle in the research time frame. The cycle will be not be repeated. The chart below shows what will happen to you during your participation in this research. The left-hand column shows the day in the cycle and the right-hand column tells you what to do on that day.

Cycle 1

Day	**What you do**
Prior to Surgery Admission	• Fill out Demographic Data Sheet, Numeric Rating Scale for pain & General Comfort Questionnaire (16-21 minutes total time)**.**
Day of Surgery	• Report for Surgery, Fill out Numeric Rating Scale (1 minute total time).
Recovery Room	• Numeric Rating Scale (1 minute total time) completed in PACU.
Admission to Room	• Numeric Rating Scale & General Comfort Questionnaire (11-16 minutes total time).
Research after Admission to Room	• Researcher will Review Data for Medications Received & gather information Numeric Rating Scale from medical record.
Conclusion	• No further information or Questionnaires Required.

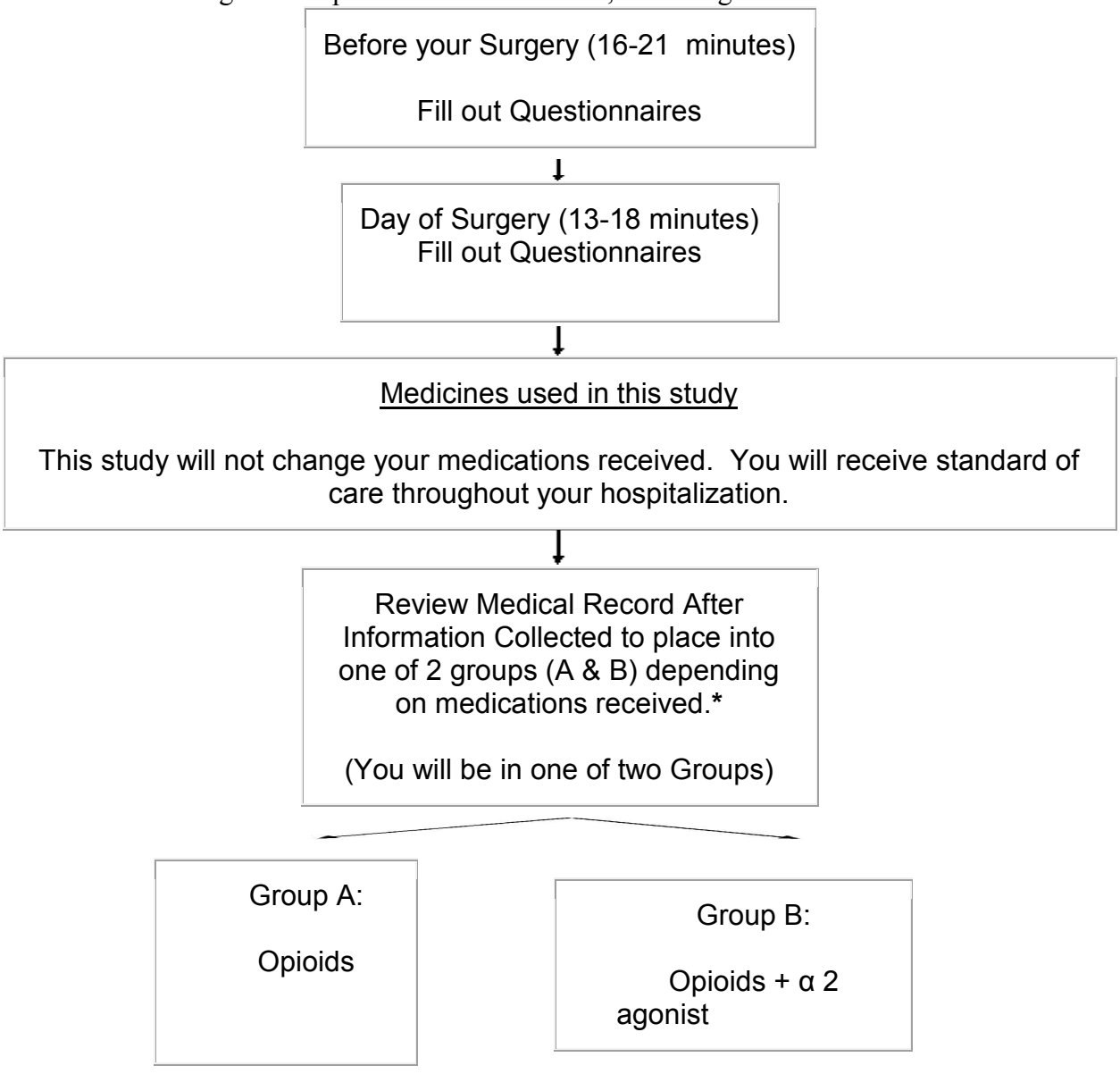
Future cycles

Day	**What you do**
Days 1-28	• No further information required. Continue with surgical treatment plan as indicated by your surgeon.

Appendix B (continued)

Study Plan

Another way to find out what will happen to you during the research study is to read the chart below. Start reading at the top and read down the list, following the lines and arrows.



Appendix B (continued)

How long will you be in the research study?

The research study will be complete after you have been admitted to your Room and have completed the final Numeric Rating Scale & General Comfort Questionnaire. Since there is no change in your care during this research, no follow up will be required. You will continue follow up with your surgeon as directed.

Can you stop being in the research study?

Yes. You can decide to stop at any time. Tell the study coordinator if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study coordinator if you are thinking about stopping so any risks can be evaluated as needed. Another reason to tell your research coordinator that you are thinking about stopping is to discuss what followup care could be most helpful for you.

Can you be removed from this research study?

The study nurse may stop you from taking part in this research study at any time if he/she believes it is in your best interest; if you do not follow the research study rules; or if the research study is stopped.

What side effects or risks can you expect from being in the research study?

The study introduces little risk for subjects. Your medical record review will reveal which group you will be placed into only after your care is complete. You will not receive any specific medications while taking part in this research. You will not require any blood work or testing as a result of participation in this research. You should talk to your study nurse about any issues that you may have while taking part in the research study.

Are there benefits to taking part in the study?

Taking part in this study may or may not make your health better. While your healthcare providers administer high quality care with monitored comfort and pain control, it would be more useful to compare the variety of treatment modalities. This study may provide information determining a best pain management strategy for this robotic laparoscopic procedure, both improving pain control and comfort for a quick recovery and expedited discharge from the hospital. Although there is no proof of this yet, we do know that the information from this study will help your healthcare team learn more about improving pain control and comfort for this specific type of surgery. This information could help future cancer patients.

Appendix B (continued)

What other choices do you have if you do not take part in this research study?
Your other choices may include:

- Getting treatment or care for your cancer without being in a study
- Taking part in another study
- Getting no treatment

Talk to your doctor about your choices before you decide if you will take part in this study.

Will your medical information be kept private?
We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

Fox Chase Cancer Center, Institutional Review Board
The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people

You will be given a separate form to review regarding the steps we will take to guard your privacy as part of your participation in the research study. By signing that additional authorization, you will be providing your consent to use and disclose information described in that form connected with your participation in this research study.

What are the costs?
Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

Will you be compensated?
You will not get paid for taking part in this research study. If you are harmed because of the research study, we will provide the medical care to treat that harm. However, you may have to pay for this treatment. Fox Chase Cancer Center has not set aside funds to pay your salary if you cannot work or for any other damages if you are harmed because of the research study.

What are your rights if you take part in this research study?
Taking part in this research study is your choice. You may choose either to take part or not to take part in the research study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Appendix B (continued)

New findings

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

Who can answer your questions about the research study?

If you have questions about:	Please Page:
This study	Kimberly A. Davis, DrNP(c), CRNA 215-308-1262
If you get sick or hurt in this study	Kimberly A. Davis, DrNP(c), CRNA 215-308-1262
If you have a concern or complaint	Director, Risk Management 215-728-2591
Your rights as a research participant while you are on this study or after the study ends	Institutional Review Board 215-214-3754
Your bills or health insurance coverage	Clinical Trial Financial Counselor 215-214-1727

Where can you get more information?

You may call the National Cancer Institute's Cancer Information Service at:

1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615

- You may also visit the NCI website at http://cancer.gov
- For NCI's clinical trials information, go to: http://cancer.govclinicaltrials/
- For NCI's general information about cancer, go to: http://cancer.gov/cancerinfo/

By signing below, you tell us that you have received all of the information you need; that you have clear answers to your questions, and that you agree to take part in the research study. You will receive a copy of this form. You may also request a copy of the research plan.

_____ _____

Signature of Participant **Date**

_____ _____

Signature of Person Obtaining Consent, Degree **Date**

By signing this form the Private Investigator obtaining consent indicates that the research participant has been fully informed of all aspects of the research study.

Appendix C

FOX CHASE
CANCER CENTER

Authorization (Permission) to Use or Disclose (Release) Protected Health Information (PHI) for Research

IRB# and Protocol ID:	IRB #11-883
Study Title:	Pain Management and Comfort in Robotic Laparoscopic Prostatectomy Patients
Principal Investigator:	Kimberly A. Davis, DrNP(c), CRNA
Coordinating Group (or Center):	Fox Chase Cancer Center
Other Sponsor(s):	Drexel University

1. What is the purpose of this form?

This form is required by the Health Insurance Portability and Accountability Act of 1996. Specifically the privacy regulation (HIPAA) permits the research investigators listed above to use and disclose health information about you for the research study identified above which has been approved by the Fox Chase Cancer Center Institutional Review Board.

The Fox Chase Cancer Center is an organization that does research to learn about the causes of cancer, and how to prevent and treat cancer. Researchers would like to use your protected health information for research. The elements of protected health information as defined by HIPAA are:

Data Elements for Protected Health Information (PHI)

- Names
- All geographic subdivisions smaller than a state (except for the first 3 digits of the zip code in some cases)
- All elements of dates (except year) for dates directly related to an individual (e.g., birth date, admission date, discharge date, date of death) and all ages over age 89 and dates indicative of that age
- Telephone numbers
- Fax numbers
- E-mail addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URL)
- Internet Protocol (IP) addresses

Appendix C (continued)

- Biometric identifiers, including finger and voice prints
- Full face photos and any comparable images
- Any other unique identifying number, characteristic, or code

2. What protected health information do the researchers want to use?
The researchers may want to copy and use the portions of your health information that they will need for their research. If you enter a research study, health information that maybe used and/or released include the following:

- Personal medical history;
- Family medical history;
- Tissue/blood/cells/DNA;
- Content of audio/video recording of sessions;
- Current and past cancer screening and lifestyle practices, medications, therapies, diagnostic tests, surgeries, and/or biopsies;
- Information from a genetic test you may have had in the past (for example, BRCA1 and/or BRCA2 testing)
- Any information collected in the Health History Questionnaire and/or other survey instruments completed during the course of the study.

You may request a blank copy of the data forms from the study doctor or his/her research staff to learn what information will be shared.

3. Why do the researchers want my protected health information?
Fox Chase Cancer Center will collect your protected health information and share it with the Fox Chase Cancer Center Biostatistical Center if you enter a research study. The center will use your information in their cancer research study.

4. Who will be able to use my protected health information?
Fox Chase Cancer Center will use your health information for research. As part of this research, it may give your information to the following groups taking part in the research. Fox Chase Cancer Center may also permit these groups to come in to review your original records that are kept by Fox Chase Cancer Center so that they can monitor the research study.

- The Fox Chase Cancer Center Biostatistical Center
- Public health agencies and other government agencies (including non-U.S.) as authorized or required by law;
- Other people or organizations assisting with research efforts of the Fox Chase Cancer Center

Appendix C (continued)

5. How will information about me be kept private?
Fox Chase Cancer Center will keep all health information private to the extent possible. Only researchers working with Fox Chase Cancer Center or the sponsor will have access to your information. Fox Chase Cancer Center or the sponsor will not release personal health information about you to others except as authorized or required by law. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

6. What happens if I do not sign this permission form?
If you do not sign this permission form, you will not be able to take part in the research study for which you are being considered.

7. If I sign this form, will I automatically be entered into the research study?
No, you cannot be entered into any research study without further discussion and separate consent. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a specific research consent form.
Treatment by your physician will not be affected by whether you provide authorization for the requested use or disclosure except if your treatment is related to research.

8. What happens if I want to withdraw my permission?
You can change your mind at any time and withdraw your permission to allow your protected health information to be used in the research. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new protected health information will be used for research. However, researchers may continue to use the protected health information that was provided before you withdrew your permission. If you sign this form and enter the research study, but later change your mind and withdraw your permission, you will be removed from the research study at that time.
To withdraw your permission, please contact the person below. She will make sure your written request to withdraw your permission is processed correctly.

Contact Name:	Kimberly A. Davis, DrNP(c), CRNA
Contact Address:	333 Cottman Avenue, Philadelphia, PA
Contact Phone and	Pager, 215 308 1262; Phone 215 728 3180; FAX 215 214 1734

9. How long will this permission last?
If you agree by signing this form that researchers can use your protected health information, this permission has no expiration date. However, as stated above, you can change your mind and withdraw your permission at any time.

Appendix C (continued)

10. What are my rights regarding access to my personal health information?
You have the right to refuse to sign this permission form. You have the right to review and/or copy records of your protected health information kept by Fox Chase Cancer Center

****

Signatures
I agree that my protected health information may be used for the research purposes described in this form.

Participant Signature: _____ Date: _____
or Legal Representative: _____ Date: _____
Printed Name of Legal Representative (if any): _____
_____HIPPA CONSENT

Appendix D

Numeric Pain Rating Scale

Located in the Fox Chase Cancer Center Employee Handbook

Nursing Standards: Section 1

https://myportal.fccc.edu/portal/c/document_library/get_file?groupId=11506&uuid=855a9c0f-d46f-40df-b4fc-1b75434dbf25

https://myportal.fccc.edu/portal/c/document_library/get_file?groupId=11506&uuid=3af5aeaa-c39a-4cca-ab8f-6d6dffc60fb6

Appendix E

IRB #11-883 Demographic Data Sheet

Please Circle ONLY ONE Answer:

1. What is the highest level of Education you have completed?
    a. None
    b. Grade School
    c. GED
    d. High School Diploma
    e. Some College (Diploma or Associate Degree)
    f. Undergraduate Degree (Bachelor's)
    g. Graduate Degree (Master's/Doctorate)

2. What is your current Marital Status?
    a. Single
    b. Married
    c. Widowed
    d. Divorced
    e. Other

3. What is your Yearly Income?
    a. < $10,000
    b. < $20,000
    c. < $25,000
    d. < $50,000
    e. < $75,000
    f. < $100,000
    g. > $100,000

4. What is your Race?
    a. Caucasian/White
    b. Black/African American
    c. Asian
    d. Latino/Hispanic
    e. Other

Appendix E (continued)

5. Do you suffer from Chronic Pain?
    a. No/Never
    b. Rarely
    c. Occasionally
    d. Yes/Sometimes
    e. Always

6. If you have Chronic Pain, please rate your pain level now using the 0-10 score. 0 = No Pain and 10 = Worst Possible Pain.
    a. _____
    b. I Do Not have Chronic Pain

7. Do you take Medications for Pain?
    a. Never
    b. Rarely
    c. Occasionally
    d. Weekly
    e. Daily
    f. Several Times Per Day

8. What is your Age?
    a. _____

9. Do you Smoke Cigarettes?
    a. Never
    b. Quit Smoking
    c. Occasionally
    d. Daily

10. Do you Exercise
    a. Never
    b. Rarely
    c. Occasionally
    d. Regularly (several times per week)

Appendix E (continued)

11. What is your Natural Hair Color?
    a. Blonde
    b. Brunette
    c. Black
    d. Red/Auburn
    e. Other

Please circle ALL that Apply:

12. Emotional Support Through
    a. Family/Friends
    b. Meditation
    c. Prayer
    d. Acupuncture/Acupressure
    e. Massage Therapy
    f. Other_____

13. Spiritual Support Through
    a. Family/Friends
    b. Meditation
    c. Prayer
    d. Acupuncture/Acupressure
    e. Massage Therapy
    f. Other_____

14. I am NOT comfortable if
    a. I am too Cold
    b. I am too Hot
    c. I am Hungry
    d. My Activity is Limited
    e. I have Pain

Appendix F

Date_____ Code #_____

GENERAL COMFORT QUESTIONNAIRE

Thank you VERY MUCH for helping me in our study of the concept COMFORT. Below are statements that may describe your comfort right now. Six numbers are provided for each question; please circle the number you think most closely matches your feeling. This is about your comfort at the moment you are answering the questions.

		Strongly Disagree					Strongly Agree
1.	There are those I can depend on when I need help	1	2	3	4	5	6
2.	I don't want to exercise	1	2	3	4	5	6
3.	My condition gets me down	1	2	3	4	5	6
4.	I feel confident	1	2	3	4	5	6
5.	I feel my life is worthwhile right now	1	2	3	4	5	6
6.	I am inspired by knowing that I am loved	1	2	3	4	5	6
7.	The sounds keep me from resting	1	2	3	4	5	6
8.	No one understands me	1	2	3	4	5	6
9.	My pain is difficult to endure	1	2	3	4	5	6
10.	I am unhappy when I am alone	1	2	3	4	5	6
11.	I do not like it here	1	2	3	4	5	6
12.	I am constipated right now	1	2	3	4	5	6
13.	I do not feel healthy right now	1	2	3	4	5	6
14.	My room makes me feel scared	1	2	3	4	5	6
15.	I am afraid of what is next	1	2	3	4	5	6

Appendix F (continued)

16. I am very tired	1	2	3	4	5	6
17. I am content	1	2	3	4	5	6
18. This chair (bed) makes me hurt	1	2	3	4	5	6
19. The views are soothing	1	2	3	4	5	6
20. My personal belongings are not here	1	2	3	4	5	6
21. I feel out of place here	1	2	3	4	5	6
22. My friends remember me with their cards and phone calls	1	2	3	4	5	6
23. I need to be better informed about my health	1	2	3	4	5	6
24. I don't have many choices	1	2	3	4	5	6
25. This room smells bad	1	2	3	4	5	6
26. I feel peaceful	1	2	3	4	5	6
27. I am depressed	1	2	3	4	5	6
28. I have found meaning in my life	1	2	3	4	5	6

Appendix G

Drexel University Office of Regulatory Research Compliance (ORRC)
Procedure for Obtaining a Letter of Reliance (Assurance)

The Office for Human Research Protections (OHRP) has made an allowance for the Institutional Review Board (IRB) of one institution to act on behalf of the relying institution's IRB via an IRB Authorization Agreement. The DUCOM IRB refers to this Authorization Agreement as a "Letter of Reliance". The intent of the agreement is to help minimize or reduce the burdens of review and redundancy in work load when two or more institutions will act together on the same protocol.

When a DU/DUCOM investigator seeks to work collaboratively with another institution, we ask that the following procedures be taken into consideration. Please note that the Letter of Reliance can only be executed with an institution which holds a valid Federal Wide Assurance number (FWA) that is not expired.

The process of finalizing the DUCOM IRB Letter of Reliance is executed by the ORRC with the other institution's IRB or their Office of Research Compliance.

There are two primary examples of how the process of securing a Letter of Reliance may apply to a DU/DUCOM investigator.

Example 1: DUCOM IRB is the IRB of record if the research is conducted at DU/DUCOM facilities which include DU/DUCOM patients or patient records, students or employees. In this example the other institution will rely on the DUCOM IRB when collaborating with DU/DUCOM faculty.
Example 2: the other institution's IRB will be the IRB of record if the research will be conducted on their property, with their patients or patient records, or with their students or employees.

Please note that the DUCOM IRB will always reserve the right of determining whether or not an agreement will be executed, as well as the right to review a proposal in addition to, and independent of any other institution's IRB.

1. Selecting the IRB of record.
    a. Research conducted at DU/DUCOM facilities, with its faculty, staff, students, patients or their patient's records, requires that the DUCOM IRB will be the IRB of record, and will review the proposal independently of another institution's IRB. The DUCOM IRB will be responsible for oversight of the related compliance activities and reporting requirements in accordance with both OHRP and FDA guidelines, (Should this be the case follow directions in #3 below).
    b. Research conducted at another institution, (regarding the examples cited above in 1a), will require the other institution to be responsible for the IRB review, related compliance activities and reporting requirements in accordance with both OHRP and FDA guidelines (Should this be the case follow directions in #4 below).

2. Once the Principal Investigator (PI)* has determined where the research will primarily take place, and who will be involved, the PI must contact their IRB and/or

Appendix G (continued)

Drexel University Request for Letter of Reliance

July 9, 2012

To Whom It May Concern:

This letter is a Request for a Reliance Agreement between Fox Chase Cancer Center and Drexel University. The Primary Investigator, Kimberly A. Davis, DrNP(c), CRNA is currently employed at Fox Chase Cancer Center as a Nurse Anesthetist and in a Doctoral Program at Drexel University for DrNP completion. This program requires research for completion.

Final IRB approval for IRB# 11-883 Fox Chase Cancer Center occurred June 8, 2012. Research entitled "Pain Management and Comfort in Robotic Laparoscopic Prostatectomy Patients". There is no funding for this research.

Key personnel at Drexel University consist of Kimberly A. Davis, DrNP(c), CRNA, Primary Investigator (Student in DrNP program). Linda Wilson, PhD is my Supervising Professor / Research Advisor. Linda Wilson, PhD, RN, CPAN, CAPA, BC, CNE, Assistant Dean for Special Projects, Simulation & CNE Accreditation, Associate Professor, College of nursing and Health Professions. Dr. Wilson will provide guidance throughout research project to graduation.

Drexel University IRB Authorization Agreement may be signed by Mr. Jack Medendorp, MS, BSN, CIP, Assistant Director for Research Compliance at Drexel University contact information phone # 215 255 7859 e-mail: Jcm29@drexel.edu Drexel University's IRB FWA# will be provided upon completion of the actual agreement by Drexel University.

Thank you for your consideration and time.

Sincerely,

Kimberly A. Davis, DrNP(c), CRNA

Appendix H

FOX CHASE
CANCER CENTER

Institutional Review Board (IRB) Authorization Agreement

Name of Institution or Organization Providing IRB Review (Institution A):
___Fox Chase Cancer Center

IRB Registration #: 00000050 Federalwide Assurance (FWA) #: 00003846
IRB Registration #: 000005828

Name of Institution Relying on the Designated IRB (Institution B):
_Drexel University

FWA #: _____

The Officials signing below agree that _Drexel University_ may rely on the designated IRB for review and continuing oversight of its human subjects research described below: (*check one*)

(___) This agreement applies to all human subjects research covered by Institution B's FWA.

(X) This agreement is limited to the following specific protocol(s):

Name of Research Project: Pain Management and Comfort in Robotic Laparoscopic Prostatectomy Patients
Name of Principal Investigator: Kimberly Davis, DrNP (c)
Sponsor or Funding Agency:___N/A_____: Award Number, if any: _____

(___) Other (*describe*):_____

The review performed by the designated IRB will meet the human subject protection requirements of **Drexel University** OHRP-approved FWA. The IRB at **Fox Chase Cancer Center** will follow written procedures for reporting its findings and actions to appropriate officials at **Drexel University**. Relevant minutes of IRB meetings will be made available to **Drexel University's ORC** upon request. **Drexel University** remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official **Fox Chase Cancer Center**:
_____ Date: 3/6/2012

Print Full Name: Michael V. Seiden, MD, PhD Institutional Title: _President and CEO_

NOTE: The IRB of Institution A must be designated on the OHRP-approved FWA for Institution B.

Signature of Signatory Official **Drexel University**:
_____ Date: _____

Print Full Name: Jack Medendorp, MS, BSN, CIP Institutional Title: Assistant Director for Research Compliance

OHRP Version Date: 03/31/2011

Appendix H (continued)

FOX CHASE
CANCER CENTER

Institutional Review Board (IRB) Authorization Agreement

Name of Institution or Organization Providing IRB Review (Institution A):
___Fox Chase Cancer Center

IRB Registration #: 00000050 Federalwide Assurance (FWA) #: 00003846
IRB Registration #: 000005828

Name of Institution Relying on the Designated IRB (Institution B):
_Drexel University

FWA #: _____

The Officials signing below agree that _Drexel University_ may rely on the designated IRB for review and continuing oversight of its human subjects research described below: (*check one*)

(___) This agreement applies to all human subjects research covered by Institution B's FWA.

(X) This agreement is limited to the following specific protocol(s):

Name of Research Project: Pain Management and Comfort in Robotic Laparoscopic Prostatectomy Patients
Name of Principal Investigator: Kimberly Davis, DrNP (c)
Sponsor or Funding Agency:___N/A_____: Award Number, if any: _____

(___) Other (*describe*):_____

The review performed by the designated IRB will meet the human subject protection requirements of **Drexel University** OHRP-approved FWA. The IRB at **Fox Chase Cancer Center** will follow written procedures for reporting its findings and actions to appropriate officials at **Drexel University**. Relevant minutes of IRB meetings will be made available to **Drexel University's ORC** upon request. **Drexel University** remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official **Fox Chase Cancer Center**:
Michael V Seiden Date: 3/6/2012

Print Full Name: Michael V. Seiden, MD, PhD Institutional Title: _President and CEO_

NOTE: The IRB of Institution A must be designated on the OHRP-approved FWA for Institution B.

Signature of Signatory Official **Drexel University**:
_____ Date: _____

Print Full Name: Jack Medendorp, MS, BSN, CIP Institutional Title: Assistant Director for Research Compliance

OHRP Version Date: 03/31/2011

Appendix H (continued)

FOX CHASE CANCER CENTER
TEMPLE HEALTH

Institutional Review Board
Federal Wide Assurance #00003846

Acknowledgment

To: Kimberly Davis, DrNP(c), CRNA

Re: IRB# 11-883

Title: Pain Management and Comfort in Robotic Laparoscopic Prostatectomy Patients

This is to inform you that the IRB acknowledges the following:

		Date
Type of action	Change in Research Staff	
Type of review	Expedited	10/23/2012
Approval expiration		
Grant number		
Protocol version		
Informed consent document		
Investigator's Brochure		
Other		

Comments:
- Addition of Marc Smaldone, MD to the research team as a Sub-Investigator.
- **IRB acknowledges addition of study staff.**

Clifford Perlis, MD, IRB Chairperson

10/23/2012
Date

Appendix H (continued)

Certificate of Completion

This is to acknowledge that

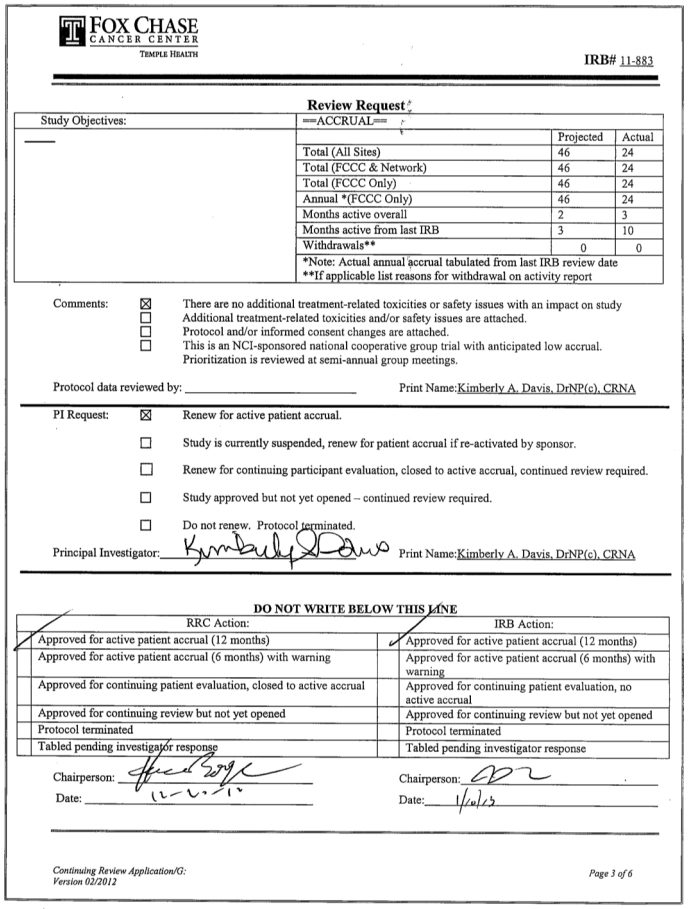
Kimberly Davis

certified in the Human Subjects Protection Program at Fox Chase Cancer Center on 10/08/2012

Jane Nice

IRB Staff, Office of the Institutional Review Board
NCI
CITI Program
Seminar
CITI COI
Other: _ _
Expiration Date: 10/07/2015

Appendix H (continued)



FOX CHASE CANCER CENTER
TEMPLE HEALTH

IRB# 11-883

Review Request

Study Objectives:	==ACCRUAL==		
		Projected	Actual
	Total (All Sites)	46	24
	Total (FCCC & Network)	46	24
	Total (FCCC Only)	46	24
	Annual *(FCCC Only)	46	24
	Months active overall	2	3
	Months active from last IRB	3	10
	Withdrawals**	0	0
	*Note: Actual annual accrual tabulated from last IRB review date **If applicable list reasons for withdrawal on activity report		

Comments:
- ☒ There are no additional treatment-related toxicities or safety issues with an impact on study
- ☐ Additional treatment-related toxicities and/or safety issues are attached.
- ☐ Protocol and/or informed consent changes are attached.
- ☐ This is an NCI-sponsored national cooperative group trial with anticipated low accrual. Prioritization is reviewed at semi-annual group meetings.

Protocol data reviewed by: _____ Print Name: Kimberly A. Davis, DrNP(c), CRNA

PI Request:
- ☒ Renew for active patient accrual.
- ☐ Study is currently suspended, renew for patient accrual if re-activated by sponsor.
- ☐ Renew for continuing participant evaluation, closed to active accrual, continued review required.
- ☐ Study approved but not yet opened – continued review required.
- ☐ Do not renew. Protocol terminated.

Principal Investigator: Kimberly A Davis Print Name: Kimberly A. Davis, DrNP(c), CRNA

DO NOT WRITE BELOW THIS LINE

RRC Action:	IRB Action:
✓ Approved for active patient accrual (12 months)	✓ Approved for active patient accrual (12 months)
Approved for active patient accrual (6 months) with warning	Approved for active patient accrual (6 months) with warning
Approved for continuing patient evaluation, closed to active accrual	Approved for continuing patient evaluation, no active accrual
Approved for continuing review but not yet opened	Approved for continuing review but not yet opened
Protocol terminated	Protocol terminated
Tabled pending investigator response	Tabled pending investigator response

Chairperson: _____ Chairperson: _____
Date: 12-2-12 Date: 1/10/13

Continuing Review Application/G: Version 02/2012 *Page 3 of 6*

Appendix H (continued)

FOX CHASE CANCER CENTER
TEMPLE HEALTH

IRB# 11-883

**********DO NOT WRITE BELOW THIS LINE********FOR IRB USE ONLY **********

Regulatory Review Requirement	Reviewed	Suggested Questions for IRB
Risk to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may be reasonably expected to result.	✓	
Frequency and extent of continuing review.	✓	Is there sufficient risk to warrant review of this protocol sooner than the standard 365 days?
Confirmation of use of approved protocol.	✓	Have all changes in the protocol to be reviewed already been reviewed and approved by the IRB?
Confirmation of use of approved consent form.	✓	Is the consent form appropriately reflective of the protocol? Is there a need to request confirmation from someone other than the PI that no changes have been made to the protocol other than those previously reviewed and approved by the IRB? Is the current consent still accurate and complete?
Review of progress of the study.	✓	What progress has been made? What changes to the protocol have been necessitated? What have been the experiences of the subjects (adverse events and benefits)?
Confirmation that the study is conducted in accordance with appropriate guidelines and regulations.	✓	Is this study being conducted in accordance with IRB policies and procedures?
Discussion of findings to date of this study or existing literature.	✓	Has any new information been discovered that may affect a subject's decision to participate or continue to participate? If so, how has this information been communicated to currently accrued subjects?
Terminated study review and notification of subjects.	n/a	Have all subjects been notified that the study has been terminated? If so, by what method?

Risk/Benefit Assessment

RISK

Regulatory definition of minimal risk: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(h)(I)).

Check appropriate risk category:

1. ✓ The research involves no more than minimal risk to subjects.
2. _____ The research involves more than minimal risk to subjects.
   a. _____ The risk(s) represents a minor increase over minimal risk, **or**
   b. _____ The risk(s) represents more than a minor increase over minimal risk.

BENEFIT

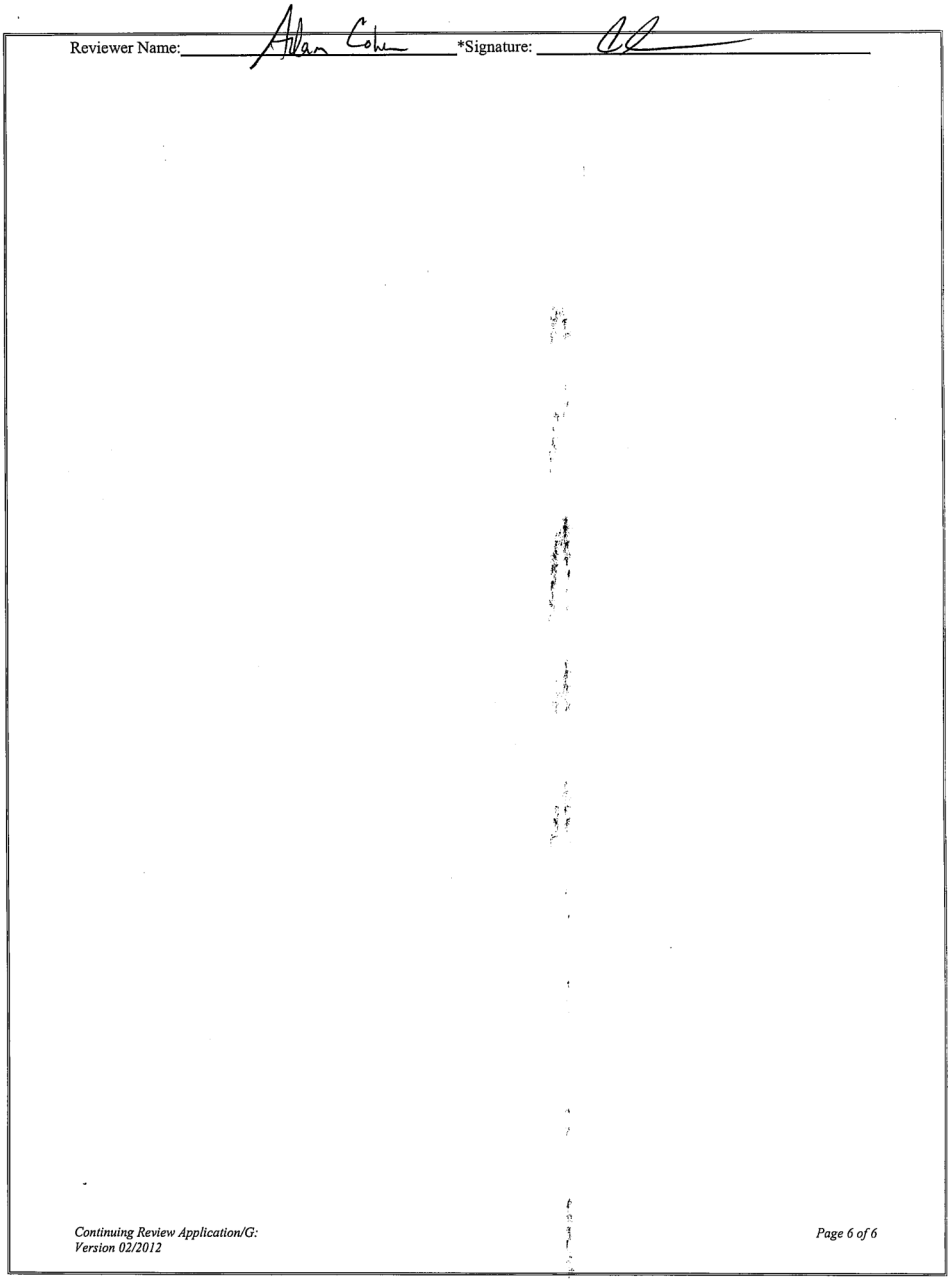
Definition: A research benefit is considered to be something of health-related, psychosocial, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participation in research is not considered to be a benefit, but rather compensation for research-related inconveniences.

Check appropriate benefit category:

1. ✓ The research involves no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition.
2. _____ The research involves the prospect of direct benefit to individual subjects.

*I verify that the regulatory criteria for approval of research have been met.

Appendix H (continued)


Reviewer Name: Allan Cohen *Signature:

Continuing Review Application/G:
Version 02/2012

Page 6 of 6

Appendix H (continued)

FOX CHASE CANCER CENTER
TEMPLE HEALTH

Continuing Review

Institutional Review Board
50 Huntingdon Pike, 2nd floor
Rockledge, PA 19046
Phone#: 215-214-3754
Fax#: 215-214-4256

IRB#: 11-883	**PI: Kimberly Davis**
Title: Pain Management and Comfort in Robotic Laparoscopic I	

Grant # (if applicable): **NONE**

Study expiration date (per Initial or Continuing Review Approval Notice) 01/09/2014
Please answer the following questions. Attach additional pages as necessary.

1. Summarize any revisions to the protocol or informed consent document/HIPAA Authorization previously reviewed and approved in the attached activity report (see page 4.)
   NO REVISIONS

2. Are there any pending revisions that have not yet been reviewed and approved by the IRB?
Please check one: ☒No ☐Yes

3. Have there been any changes to the risks and/or benefits based on the results obtained from the study?
Please check one. ☒ No ☐ Yes: please discuss:____

(If you answered yes, please discuss whether 1) changes have been previously incorporated into the informed consent document, 2) have been submitted to the IRB as a study amendment and are presently under review or, 3) are not required).

4. Have unexpected events, toxicity or complications occurred? Does the protocol or informed consent document need to be changed?
Please check one. ☒ No ☐ Yes: please discuss:____

5. Has information (publications, presentations, etc.) become available since starting this study that indicates a need to modify the study (protocol or consent)?
Please check one. ☒ No ☐Yes: please discuss:____

6. Have there been any grievances or complaints received from study participants about this study?
Please check one. ☒ No ☐ Yes: please discuss:____

Appendix H (continued)

7. Do you or any other person responsible for the design, conduct, or reporting of this research have a financial or other conflict of interest as defined by the Institution or IRB Conflict of Interest Policy that would affect this research and has not previously been disclosed?

Please check one. ☒ No ☐Yes: please discuss: ____

IRB# 11-883

8. Has the study been closed to participant accrual since the date of the initial approval or last continuing review?

☐ No ☒Yes: Date: **2/8/2013** Reason: **Both Groups Were Filled**

9. Briefly summarize the research results/findings to date, including the progress of the study as compared to the hypothesis (if the study is a multi-center study, please describe or attach the reports from the other sites or the study sponsor).

I am in the process of statistical calculations to determine if there is any variation between Group A & Group B and/or the relationship between pain and comfort in the postoperative setting of this group.

Specific Aim 1 is to explore the effect of 2 groups of pharmaceutical regimens on pain and comfort in the laparoscopic robotic prostatectomy patient. The null hypothesis: Pain and comfort will not vary among the two pharmaceutical regimens.
Group A: Opioids
Group B: Opioids + α 2 agonist

Specific Aim 2: The specific aim 2 is to explore the relationship between pain and comfort in post-operative RALP patient. The null hypothesis: Decreased pain will not be associated with increased comfort

Recruitment of Subjects: **(check all that apply):**

☐ *Physician Referrals*
☐ *Clinic*
☐ *Calls to CIS*
☐ *Advertising*
☐ *Website*
☒ *Other (explain)*
Recruitment through Urology department when scheduled for RALP procedure

Signature of PI: ____Kimberly A. Davis, DrNP(c), CRNA_____ ***Date***: 12/12/13

Checklist to Include with this Form:
X Application for Continuing Review (including Review Request, Activity Report and Reviewer Evaluation, one copy of newest protocol including all changes)
X Electronic Copy of currently approved Informed Consent Document/HIPAA
N/A Data Safety Monitoring Report (if applicable)

Appendix H (continued)

IRB #11-883

Review Request

Study Objectives:	==ACCRUAL==		
____		Projected	Actual
	Total (All Sites)	46	48
	Total (FCCC & Network)	46	48
	Total (FCCC Only)	46	48
	Annual *(FCCC Only)		
	Months active overall	1-3	5
	Months active from last IRB	2	2
	Withdrawals**	0	0
	*Note: Actual annual accrual tabulated from last IRB review date **If applicable list reasons for withdrawal on activity report		

Comments: ☒ There are no additional treatment-related toxicities or safety issues with an impact on study

☐ Additional treatment-related toxicities and/or safety issues are attached.

☐ Protocol and/or informed consent changes are attached.

☐ This is an NCI-sponsored national cooperative group trial with anticipated low accrual. Prioritization is reviewed at semi-annual group meetings.

Protocol data reviewed by: Print Name:

PI Request: ☐ Renew for active patient accrual.

☐ Study is currently suspended, renew for patient accrual if re-activated by sponsor.

☒ Renew. Study is closed to new accrual but remains active for treatment and/or follow-up of enrolled participants or data analysis - continuing review required.

☐ Study approved but not yet activated – continuing review required.

☐ Do not renew. Protocol terminated.

Principal Investigator: Kimberly A. Davis, DrNP(c), CRNA Print Name: Kimberly A. Davis, DrNP(c), CRNA

DO NOT WRITE BELOW THIS LINE

	RRC Action:		IRB Action:
	Approved for active patient accrual (12 months)		Approved for active patient accrual (12 months)
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	Protocol terminated		Protocol terminated
	Tabled pending investigator response		Tabled pending investigator response

Chairperson: _____

Date: _____

Chairperson: _____

Date: _____

Appendix H (continued)

IRB #11-883

Activity Report

Review/Approval and Activity* [1]

Date	*Activity**	*Comments*

*Activities include amendments, withdrawals[1] and reasons, adverse events, unanticipated problems or outcomes, changes to the consent form, suspensions, closures and terminations.

1 Include subjects withdrawn from the study or been withdrawn from the study by the investigator

USE ADDITIONAL PAGES AS NECESSARY

Appendix H (continued)

IRB #11-883

Summary of Accrual (FCCC Only)

*Subject ID***	*Sex*	*Race*	*Start Date* *End Date*	*Date of Death*

**Subject ID should be a code, rather than subject identifiable information.

USE ADDITIONAL PAGES AS NECESSARY

Appendix H (continued)

IRB #11-883
**********DO NOT WRITE BELOW THIS LINE********FOR IRB USE ONLY **********

Regulatory Review Requirement	Reviewed	Suggested Questions for IRB
Risk to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may be reasonably expected to result.		
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Discussion of findings to date of this study or existing literature.		Has any new information been discovered that may affect a subject's decision to participate or continue to participate? If so, how has this information been communicated to currently accrued subjects?
Terminated study review and notification of subjects.		Have all subjects been notified that the study has been terminated? If so, by what method?

Risk/Benefit Assessment

RISK

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Check appropriate benefit category:

1. _____ The research involves no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition.
2. _____ The research involves the prospect of direct benefit to individual subjects.

*I verify that the regulatory criteria for approval of research have been met.

Reviewer Name:_____*Signature: _____

Appendix H (continued)

FOX CHASE
CANCER CENTER

Authorization (Permission) to Use or Disclose (Release) Protected Health Information (PHI) for Research

IRB# and Protocol ID:	IRB #11-883
Study Title:	Pain Management and Comfort in Robotic Laparoscopic Prostatectomy Patients
Principal Investigator:	Kimberly A. Davis, DrNP(c), CRNA
Coordinating Group (or Center):	Fox Chase Cancer Center
Other Sponsor(s):	Drexel University

2. What is the purpose of this form?

This form is required by the Health Insurance Portability and Accountability Act of 1996. Specifically the privacy regulation (HIPAA) permits the research investigators listed above to use and disclose health information about you for the research study identified above which has been approved by the Fox Chase Cancer Center Institutional Review Board.

The Fox Chase Cancer Center is an organization that does research to learn about the causes of cancer, and how to prevent and treat cancer. Researchers would like to use your protected health information for research. The elements of protected health information as defined by HIPAA are:

Data Elements for Protected Health Information (PHI)

- Names
- All geographic subdivisions smaller than a state (except for the first 3 digits of the zip code in some cases)
- All elements of dates (except year) for dates directly related to an individual (e.g., birth date, admission date, discharge date, date of death) and all ages over age 89 and dates indicative of that age
- Telephone numbers
- Fax numbers
- E-mail addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URL)
- Internet Protocol (IP) addresses

Appendix H (continued)

- Biometric identifiers, including finger and voice prints
- Full face photos and any comparable images
- Any other unique identifying number, characteristic, or code

2. What protected health information do the researchers want to use?

The researchers may want to copy and use the portions of your health information that they will need for their research. If you enter a research study, health information that maybe used and/or released include the following:

- Personal medical history;
- Family medical history;
- Tissue/blood/cells/DNA;
- Content of audio/video recording of sessions;
- Current and past cancer screening and lifestyle practices, medications, therapies, diagnostic tests, surgeries, and/or biopsies;
- Information from a genetic test you may have had in the past (for example, BRCA1 and/or BRCA2 testing)
- Any information collected in the Health History Questionnaire and/or other survey instruments completed during the course of the study.

You may request a blank copy of the data forms from the study doctor or his/her research staff to learn what information will be shared.

3. Why do the researchers want my protected health information?

Fox Chase Cancer Center will collect your protected health information and share it with the Fox Chase Cancer Center Biostatistical Center if you enter a research study. The center will use your information in their cancer research study.

4. Who will be able to use my protected health information?

Fox Chase Cancer Center will use your health information for research. As part of this research, it may give your information to the following groups taking part in the research. Fox Chase Cancer Center may also permit these groups to come in to review your original records that are kept by Fox Chase Cancer Center so that they can monitor the research study.

- The Fox Chase Cancer Center Biostatistical Center
- Public health agencies and other government agencies (including non-U.S.) as authorized or required by law;
- Other people or organizations assisting with research efforts of the Fox Chase Cancer Center

5. How will information about me be kept private?

Fox Chase Cancer Center will keep all health information private to the extent possible. Only researchers working with Fox Chase Cancer Center or the sponsor will have access to your information. Fox Chase Cancer Center or the sponsor will not release personal health information about you to others except as authorized or required by law. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

Appendix H (continued)

6. What happens if I do not sign this permission form?

If you do not sign this permission form, you will not be able to take part in the research study for which you are being considered.

7. If I sign this form, will I automatically be entered into the research study?

No, you cannot be entered into any research study without further discussion and separate consent. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a specific research consent form.
Treatment by your physician will not be affected by whether you provide authorization for the requested use or disclosure except if your treatment is related to research.

8. What happens if I want to withdraw my permission?

You can change your mind at any time and withdraw your permission to allow your protected health information to be used in the research. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new protected health information will be used for research. However, researchers may continue to use the protected health information that was provided before you withdrew your permission. If you sign this form and enter the research study, but later change your mind and withdraw your permission, you will be removed from the research study at that time.

To withdraw your permission, please contact the person below. She will make sure your written request to withdraw your permission is processed correctly.

Contact Name:	Kimberly A. Davis, DrNP(c), CRNA
Contact Address:	333 Cottman Avenue, Philadelphia, PA
Contact Phone and FAX:	Pager, 215 308 1262; Phone 215 728 3180; FAX 215 214 1734

9. How long will this permission last?

If you agree by signing this form that researchers can use your protected health information, this permission has no expiration date. However, as stated above, you can change your mind and withdraw your permission at any time.

10. What are my rights regarding access to my personal health information?

You have the right to refuse to sign this permission form. You have the right to review and/or copy records of your protected health information kept by Fox Chase Cancer Center.

****

Signatures

I agree that my protected health information may be used for the research purposes described in this form.

Participant Signature: _____ Date: _____
or Legal Representative: _____ Date: _____
Printed Name of Legal Representative (if any): _____

Appendix H (continued)

FOX CHASE
CANCER CENTER

INFORMED CONSENT DOCUMENT

Pain Management and Comfort in Robotic Laparoscopic Prostatectomy Patients

Principal Investigator: Kimberly A. Davis, DrNP(c) CRNA

This is a clinical trial, a type of research study. Your study nurse will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You should discuss your decision with your friends and family. You will also discuss it with your health care team. If you have any questions, you can ask your study nurse for more explanation.
You are being asked to take part in this research study because you have Prostate Cancer and have chosen Robotic Laparoscopic Prostatectomy surgery.
The sponsor of this study is **Fox Chase Cancer Center.**

Why is this research study being done?
The purpose of this study is to find out the best pain management strategy after your procedure. We would like to find out what combination of medications work best after your surgery. You will receive the same care and medications chosen by your anesthesia provider whether or not you participate in this study. These medications will be reviewed after your surgery is complete and compared to your pain score. We do not know if you will benefit from this research study. We can use what we learn from this research study to help other people with the same disease.

How many people will take part in this research study?
About 23 people for each group (two groups) will be needed for this research. A total of 46 people will take part in this research study if able to fill groups evenly.

What will happen if you take part in this research study?
Before you begin the research study... You will be given a Demographic Data Sheet to complete. Prior to surgery, The Numerical Rating Scale (NRS) and Comfort Questionnaire will be completed. Postoperatively, upon arrival to the Recovery Room (Post Anesthesia Care Unit PACU) and at PACU discharge, the NRS will be administered. The Numerical Rating Scale will be completed in the recovery area by the PACU RN. Upon PACU discharge to medical/surgical room, the Numerical Rating Scale and Comfort Questionnaire will be completed. Evaluation of medical record will provide medications received intraoperatively. This will place participant in Group A or B. Further medications will be recorded from PACU setting.

No tests or procedures will be required to participate in this study.

Appendix H (continued)

During the research study...

If you choose to take part in this research study, then you will be asked to participate in answering the Comfort Questionnaire information. The Numerical Rating Scale and medications provided during your care are part of regular cancer treatment.

- ***Comfort Questionnaire***

You will receive the Numerical Rating Scale as a part of regular cancer care. This is being done no different because you are in this research study.

- ***Numerical Rating Scale***

You will need no tests or procedures for this research study. Your chart will be reviewed after your surgery to determine what medications you received and review your Numerical Rating Scale Scores.

- ***Medication Review for group placement***

Questionnaires

We are asking you to fill out a Demographic Data Form which is a Questionnaire that will be filled out one time only and takes < 5 minutes for completion.

We are asking you to fill out questionnaires about comfort for this research study. This questionnaire will tell us about your pain and your comfort. You will spend 10-15 minutes to fill out the comfort questionnaire. We will ask you to fill this out before your surgery one time and one time after your surgery to total two times during this research study.

You do not have to answer any questions that make you uneasy. Whether or not you answer any question will not affect your medical care. We will keep the paper copies of the questionnaires in a locked file to protect your privacy.

Appendix H (continued)

Study Chart

You will receive **a questionnaire** one time before your surgery and one time after your surgery describing your comfort for this research study. This [two questionnaires from before your surgery until you return to your room] is called a cycle in the research time frame. The cycle will be not be repeated. The chart below shows what will happen to you during your participation in this research. The left-hand column shows the day in the cycle and the right-hand column tells you what to do on that day.

Cycle 1

Day	**What you do**
Prior to Surgery Admission	• Fill out Demographic Data Sheet, Numeric Rating Scale for pain & General Comfort Questionnaire (16-21 minutes total time)**.**
Day of Surgery	• Report for Surgery, Fill out Numeric Rating Scale (1 minute total time).
Recovery Room	• Numeric Rating Scale (1 minute total time) completed in PACU.
Admission to Room	• Numeric Rating Scale & General Comfort Questionnaire (11-16 minutes total time).
Research after Admission to Room	• Researcher will Review Data for Medications Received & gather information Numeric Rating Scale from medical record.
Conclusion	• No further information or Questionnaires Required.

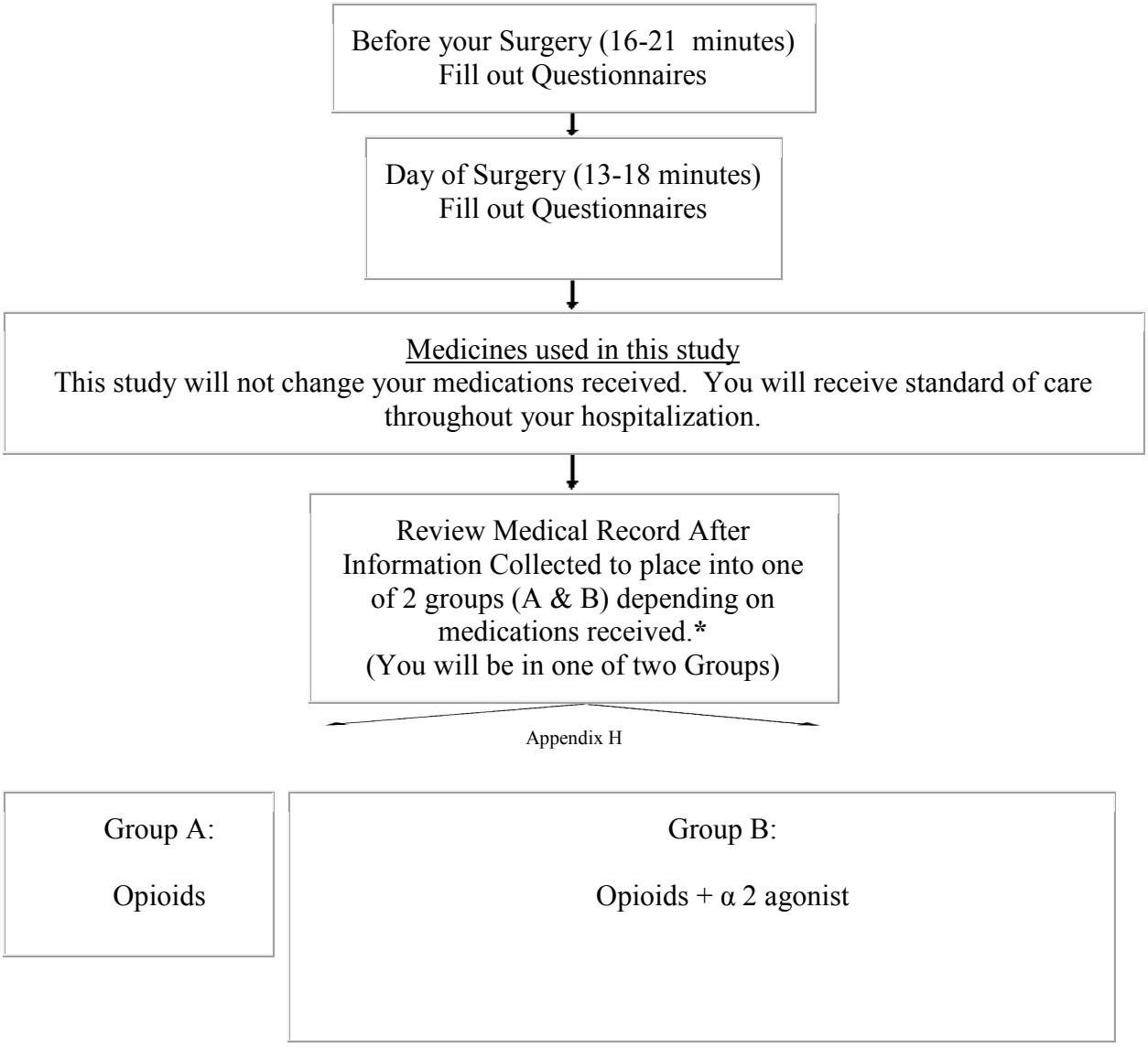
Future cycles

Day	**What you do**
Days 1-28	• No further information required. Continue with surgical treatment plan as indicated by your surgeon.

Appendix H (continued)

Study Plan

Another way to find out what will happen to you during the research study is to read the chart below. Start reading at the top and read down the list, following the lines and arrows.



How long will you be in the research study?

The research study will be complete after you have been admitted to your Room and have completed the final Numeric Rating Scale & General Comfort Questionnaire. Since there is no change in your care during this research, no follow up will be required. You will continue follow up with your surgeon as directed.

Appendix H (continued)

Can you stop being in the research study?
Yes. You can decide to stop at any time. Tell the study coordinator if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study coordinator if you are thinking about stopping so any risks can be evaluated as needed. Another reason to tell your research coordinator that you are thinking about stopping is to discuss what followup care could be most helpful for you.

Can you be removed from this research study?
The study nurse may stop you from taking part in this research study at any time if he/she believes it is in your best interest; if you do not follow the research study rules; or if the research study is stopped.

What side effects or risks can you expect from being in the research study?
The study introduces little risk for subjects. Your medical record review will reveal which group you will be placed into only after your care is complete. You will not receive any specific medications while taking part in this research. You will not require any blood work or testing as a result of participation in this research. You should talk to your study nurse about any issues that you may have while taking part in the research study.

Are there benefits to taking part in the study?
Taking part in this study may or may not make your health better. While your healthcare providers administer high quality care with monitored comfort and pain control, it would be more useful to compare the variety of treatment modalities. This study may provide information determining a best pain management strategy for this robotic laparoscopic procedure, both improving pain control and comfort for a quick recovery and expedited discharge from the hospital. Although there is no proof of this yet, we do know that the information from this study will help your healthcare team learn more about improving pain control and comfort for this specific type of surgery. This information could help future cancer patients.

What other choices do you have if you do not take part in this research study?
Your other choices may include:

- Getting treatment or care for your cancer without being in a study
- Taking part in another study
- Getting no treatment

Talk to your doctor about your choices before you decide if you will take part in this study.

Appendix H (continued)

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- Fox Chase Cancer Center, Institutional Review Board
- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people

You will be given a separate form to review regarding the steps we will take to guard your privacy as part of your participation in the research study. By signing that additional authorization, you will be providing your consent to use and disclose information described in that form connected with your participation in this research study.

What are the costs?

Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

Will you be compensated?

You will not get paid for taking part in this research study. If you are harmed because of the research study, we will provide the medical care to treat that harm. However, you may have to pay for this treatment. Fox Chase Cancer Center has not set aside funds to pay your salary if you cannot work or for any other damages if you are harmed because of the research study.

What are your rights if you take part in this research study?

Taking part in this research study is your choice. You may choose either to take part or not to take part in the research study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

New findings

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

Appendix H (continued)

Who can answer your questions about the research study?

If you have questions about:	Please Page:
This study	Kimberly A. Davis, DrNP(c), CRNA 215-308-1262
If you get sick or hurt in this study	Kimberly A. Davis, DrNP(c), CRNA 215-308-1262
If you have a concern or complaint	Director, Risk Management 215-728-2591
Your rights as a research participant while you are on this study or after the study ends	Institutional Review Board 215-214-3754
Your bills or health insurance coverage	Clinical Trial Financial Counselor 215-214-1727

Where can you get more information?

You may call the National Cancer Institute's Cancer Information Service at:

1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615

- You may also visit the NCI website at http://cancer.gov
- For NCI's clinical trials information, go to: http://cancer.govclinicaltrials/
- For NCI's general information about cancer, go to: http://cancer.gov/cancerinfo/

By signing below, you tell us that you have received all of the information you need; that you have clear answers to your questions, and that you agree to take part in the research study. You will receive a copy of this form. You may also request a copy of the research plan.

_____ _____

Signature of Participant **Date**

_____ _____

Signature of Person Obtaining Consent, Degree **Date**

By signing this form the Private Investigator obtaining consent indicates that the research participant has been fully informed of all aspects of the research study.

Appendix H (continued)

FOX CHASE CANCER CENTER	Recruitment Consent/Assent Process Information Form	Institutional Review Board 50 Huntingdon Pike, 2nd floor Rockledge, PA 19046

Recruitment Consent/Assent IRB#: 11-883	PI: Kimberly A. Davis, DrNP(c)	Date: 1/27/2012

Title: Pain Management and Comfort in Robotic Laparoscopic Prostatectomy Patients

Resources

1. **Do you have the resources (i.e. adequate facilities, staff, availability of psychological resources) you need to complete this study?** ■ Yes ☐ No If no, please explain

_____

Approach and Recruitment Procedures

1. **When will the participants be approached? (check all that apply)**
   ☐ Prior to coming to FCCC for clinic visit ☐ During Admission
   ■ At clinic visit/In clinic ☐ After discharge or clinic visit
   ☐ Other (explain) _____

2. **How will the participants be approached? (check all that apply)**
   ■ Phone ☐ Mail/letter ■ Personal Contact ☐ Other (explain) _____

3. **Who will initiate contact about the study with the participants? (check all that apply)**
   ■ PI Kimberly A. Davis, DrNP(c), CRNA ☐ Recruitment Specialist ☐ Research coordinator
   ■Other (please list by title)

Rosalia Viterbo, MD, FACS
Robert G Uzzo, MD, FACS
Richard E Greenberg, MD, FACS
David Y T Chen, MD, FACS
Alexander Kutikov, MD

4. **Do you <u>intend</u> to enroll any research participants from the following "vulnerable" categories? *<u>If yes, describe additional safeguards that are included in the protocol to insure the safety and welfare of these vulnerable populations.</u>**
   ☐ ***YES** ■ **NO**
   ☐ Prisoners ☐ Minors (under 18 years of age) ☐ Pregnant woman (If yes, you must complete question 4a)
   ☐ Decisionally Impaired (If checked, complete below)
   If some or all subjects will be decisionally impaired, describe how capacity for consent will be determined:

Appendix H (continued)

☐ Capacity Assessment by: _____
☐ Other (specify

_____

Will a legally authorized representative be utilized? *YES ☐ NO ☐
Describe Additional safeguards:

_____

_____

☐ Students to be recruited in their educational setting, i.e. in class or at school
☐ Employees, student, or volunteers directly supervised by PI or sub-investigator
☐ Employees of Research Site or Sponsor
☐ Others Vulnerable to Coercion (Specify) _____

4a. If you plan to enroll pregnant women, <u>complete the following</u>: ☐ **N/A**

As required by Federal Regulations, I assure the Board of the following: (45 CFR 46.204 (h), (i), (j))

- No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
- Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy, and
- Individuals engaged in the research will have no part in determining the viability of a neonate.

_____ _____

Signature of PI Date

Appendix H (continued)

FOX CHASE CANCER CENTER	Recruitment Consent/Assent Process	Institutional Review Board 50 Huntingdon Pike, 2nd floor

IRB #11-883

5. Approximate ethnic makeup of population to be recruited for this research:

___25% African-American ____4% Asian _____% Pacific Islander ____10% Middle Eastern
___68% Caucasian ____3% Hispanic _____% Native American/First Nations
_____% Other: _____

6. Check any of the following methods that the PI will use to recruit research participants for this study:

- ■ Advertising *(All recruitment materials must be approved by FCCC IRB before use)*
- ☐ From a database for which research participants have given prior permission to be contacted for research studies
- ■ From personal contact (e.g., patients, students)
- ☐ Referrals *(referral fees are not allowed by FCCC IRB)*
- ☐ Phone script
- ☐ Other (specify): _____

PLEASE NOTE – for HIPAA compliance, you may need an authorization from the research participant or a waiver of authorization before you can use or disclose identifiable health information for research screening or recruitment purposes. This may affect your ability to recruit research participants into this study. For more information on HIPAA requirements for research and additional HIPAA-related forms, http://www.fccc.edu/research/institutional_review/index.html

Consent/Assent Procedures

7. FCCC IRB expects that the research participant consent process will be conducted under the following conditions:

- Will take place without undue influence or coercion.
- Will allow the research participants adequate time to consider the research before signing.
- Will be conducted in a private place and manner.
- Will be conducted with words understandable to research participants.
- The person obtaining consent will invite questions from the research participants.
- The research participant will be allowed to take home an unsigned copy of the informed consent document to share with family and friends prior to enrollment.
- The research participant will be given a signed and dated copy of the informed consent document for their records if enrolled.
- Non-English speaking research participants will be provided with a certified translation of the approved informed consent document in the research participant's first language. The translation must be approved by FCCC IRB.

Indicate one of the following and attach written explanation where instructed:

- ■ The consent process will meet all of the above conditions.
- ☐ N/A, waiver of consent requested.
- ☐ The consent process will not satisfy all of the above conditions, as it will **take place in emergency situations; a written explanation of the proposed consent process is attached.**
  NOTE: Please contact FCCC IRB for an explanation of submission requirements.
- ☐ The consent process will not satisfy all of the above conditions, and the consent **will not be obtained in an emergency situation. A written explanation of the proposed consent process and the reason one or more conditions cannot be met is attached** (for example, research participants are to be recruited in an outdoor public setting where a private consent discussion is not practicable).

Appendix H (continued)

FOX CHASE CANCER CENTER	**Recruitment Consent/Assent Process Information Form**	**Institutional Review Board** **50 Huntingdon Pike, 2nd floor** **Rockledge, PA 19046**

IRB #11-883

8. If any of your research participants do not speak English, explain how the person obtaining consent will communicate with the participant in a language understandable to the research participants/parents/legally authorized representatives?

a. ■ All research participants speak and read English

b. ☐ Some of my research participants may not speak and/or read English (informed consent must be in the language of the participant)

If box (**b**.) is checked, explain how informed consent will be obtained for Non-English speakers.

☐ Translated Informed Consent Document (Translator name, if known_____)

☐ Short Form with verbal presentation in language of participant

9. In addition to the informed consent document, what else do you do to confirm the participant's or guardian(s) understanding of the research? (Check all that apply)

■ Provide brochure
☐ Conference with an interpreter
☐ Conference with patient and family member
☐ Arrange time for follow-up discussion
☐ Other (describe): _____

For Social Sciences Studies Only

10. Is any deception (withholding of complete information) required for the validity of this activity?

☐ *YES ☐ NO

*If yes, please explain why it is necessary and provide a copy of the debriefing procedure to be used at the conclusion of the study.

_____

_____

Principal Investigator: __Kimberly A. Davis, DrNP(c) _____
(PRINT NAME)

_____Date: _____
(SIGNATURE)

Appendix H (continued)

FOX CHASE CANCER CENTER
TEMPLE HEALTH

Institutional Review Board
Federal Wide Assurance #00003846

APPROVAL OF PROTOCOL

April 25, 2014

Kimberly A. Davis, DrNP(c), CRNA

Dear Kimberly A. Davis:

On 04/25/2014, the IRB Vice-Chairperson reviewed the following protocol:

Type of Review:	Modification
Title:	Pain Management and Comfort in Robotic Laparoscopic Prostatectomy Patients
Investigator:	Kimberly A. Davis, DrNP(c), CRNA
IRB ID:	11-883
Sponsors:	Fox Chase Cancer Center
Grant Title:	N/A
Grant ID:	N/A
IND, IDE or HDE:	None
Documents Reviewed:	*Modification Application; Tracked Protocol Document, Version 3.0, dated 03/17/2014*

- Amendment includes a change in statistician
- The amendment meets the requirements for expedited review in accordance with the federally defined categories of expedited review outlined in 45 CFR 46.110 (b)(2) and 21 CFR 56.110 (b)(2).
- Upon review the submission meets the criteria for the approval of research outlined in 45 CFR 46.111

Sincerely,

Eric Tetzlaff, PA-C, IRB Vice-Chairperson

Appendix H (continued)

CONDITIONS OF APPROVAL

1. No subjects may be involved in any study procedure prior to the IRB approval date or after the expiration date. (45 CFR 46.109 (a) and (d))
2. Changes, amendments, and updates to the protocol or informed consent document(s) must be submitted through the RRC for review and approval by the IRB prior to the activation of the changes. This includes any change of investigator.
3. All unanticipated and serious adverse events must be reported to the IRB within 48 hours of discovery. (45 CFR 46.103(b)(5))
4. Only informed consent documents with a valid electronic approval or stamp may be presented to subjects. All informed consent documents signed by subjects enrolled in the study must be retained on file. The Internal Audit Committee conducts periodic audits of protocol records, and consent documentation is part of these audits. (45 CFR 46.116; 45 CFR 46.117)
5. **Federal regulations require review of an approved study not less than once per 12-month period. In order to ensure timely processing of your review, the IRB suggests submitting your application 90 days prior to expiration. Failure to submit an application in a timely fashion may result in expiration of the study, at which point new subjects may not be enrolled and all research related activities must stop.**

Appendix H (continued)

FOX CHASE CANCER CENTER
TEMPLE HEALTH

Institutional Review Board
Federal Wide Assurance #00003846

MODIFICATIONS REQUIRED TO SECURE APPROVAL

January 15, 2014
Kimberly Davis, DrNP, CRNP

Dear Kimberly:

On January 15, 2014 the IRB reviewed the following protocol:

Type of Review:	Modification
Title:	Pain Management and Comfort in Robotic Laparoscopic Prostatectomy Patients
Investigator:	Kimberly Davis, DrNP, CRNP
IRB ID:	11-883
Funding:	Fox Chase Cancer Center
Grant Title:	None
Grant ID:	None
IND, IDE or HDE:	None
Documents Reviewed:	Continuing Review Application/RRC Approval Protocol Version 2.0 dated 06/06/2012

The IRB determined that modifications are required to approve the protocol. The modifications required and their reasons are listed here:

Required Change	Reason for Change
• Within the protocol it states that there will be 46 participants in this study but within the continuing review application there are 48 participants reflected. A Protocol Violation form will need to be completed and submitted to explain the over enrollment. An amendment will also need to be completed and submitted increasing the accrual numbers.	• The projected accrual number exceeded by 2 participants.

Appendix H (continued)

Please submit:

- A letter with a point-by-point response to the above changes indicating whether you agree or do not agree with each requested change.
- A copy of all revised documents in "Tracked Changes" format or similarly notated to indicate what changes were made.
- A "clean" copy of all revised and requested additional documents.

If a response is not received by close of business on **February 15, 2014** the IRB will withdraw this offer.

Should you disagree with these requested changes, your response will be reviewed by the IRB. At your request, you can respond in person to the IRB.

Sincerely,

IRB Vice-Chairperson/Eric Tetzlaff, PA-C

Appendix H (continued)

Kimberly A. Davis, DrNP(c), CRNA

Fox Chase Cancer Center: IRB 11-883

January 16, 2014

Pain Management and Comfort in Robotic Laparoscopic Prostatectomy Patients

Point-by-point response to changes for protocol

Required Change	Reason for Change
• Within the protocol it states that there will be 46 participants in this study but within the continuing review application there are 48 participants reflected. A Protocol Violation form will need to be completed and submitted to explain the over enrollment. An amendment will also need to be completed and submitted increasing the accrual numbers.	• The projected accrual number exceeded by 2 participants.

I will make any necessary changes but did not realize that this was required since both groups were not full and it took 2 extra participants to fill both groups evenly (it was random and could have taken many more). As per my protocol page 12 states that collection shall continue until both groups are filled. The 46 was a minimum number if evenly filled. I have copied and pasted this sentence below for further review, in addition to showing the two groups.

9.0.3

Determination of Sample Size for two groups

Group A: Opioids

Group B: Opioids + α 2 agonist

Recruitment will continue until both groups A & B of 23 per group are filled. This will assume 15% attrition.

With the above statement in the protocol, I do not agree that a violation is in effect, however; if the IRB feels that this has violated the protocol, I will fill out the necessary changes and submit.

Appendix H (continued)

FOX CHASE CANCER CENTER
TEMPLE HEALTH

Continuing Review Application

Institutional Review Board
50 Huntingdon Pike, 2nd floor
Rockledge, PA 19046
Phone#: 215-214-3754
Fax#: 215-214-4256

IRB#: 11-883	PI: Kimberly Davis	Date: 12/12/13

Title: Pain Management and Comfort in Robotic Laparoscopic Prostatectomy Patients

Grant # (if applicable): **NONE**

Study expiration date (per Initial or Continuing Review Approval Notice) 01/09/2014

Please answer the following questions. Attach additional pages as necessary.

1. Summarize any revisions to the protocol or informed consent document/HIPAA Authorization previously reviewed and approved in the attached activity report (see page 4.) **NO REVISIONS**

2. Are there any pending revisions that have not yet been reviewed and approved by the IRB?
   Please check one: ☒No ☐Yes

3. Have there been any changes to the risks and/or benefits based on the results obtained from the study?
   Please check one. ☒ No ☐ Yes: please discuss:____

(If you answered yes, please discuss whether 1) changes have been previously incorporated into the informed consent document, 2) have been submitted to the IRB as a study amendment and are presently under review or, 3) are not required).

4. Have unexpected events, toxicity or complications occurred? Does the protocol or informed consent document need to be changed?
   Please check one. ☒ No ☐ Yes: please discuss:____

5. Has information (publications, presentations, etc.) become available since starting this study that indicates a need to modify the study (protocol or consent)?
   Please check one. ☒ No ☐Yes: please discuss:____

6. Have there been any grievances or complaints received from study participants about this study?
   Please check one. ☒ No ☐ Yes: please discuss:____

7. Do you or any other person responsible for the design, conduct, or reporting of this research have a financial or other conflict of interest as defined by the Institution or IRB Conflict of Interest Policy that would affect this research and has not previously been disclosed?
   Please check one. ☒ No ☐Yes: please discuss: ____

Rec'd 1/3/14 gv

Appendix H (continued)

IRB# 11-883

8. Has the study been closed to participant accrual since the date of the initial approval or last continuing review?
   ☐ No ☒Yes: Date: **2/8/2013** Reason: **Both Groups Were Filled**

9. Briefly summarize the research results/findings to date, including the progress of the study as compared to the hypothesis (if the study is a multi-center study, please describe or attach the reports from the other sites or the study sponsor).

   I am in the process of statistical calculations to determine if there is any variation between Group A & Group B and/or the relationship between pain and comfort in the postoperative setting of this group.

   Specific Aim 1 is to explore the effect of 2 groups of pharmaceutical regimens on pain and comfort in the laparoscopic robotic prostatectomy patient. The null hypothesis: Pain and comfort will not vary among the two pharmaceutical regimens.
   Group A: Opioids
   Group B: Opioids + α 2 agonist

   Specific Aim 2: The specific aim 2 is to explore the relationship between pain and comfort in post-operative RALP patient. The null hypothesis: Decreased pain will not be associated with increased comfort.

Recruitment of Subjects: **(check all that apply):**

☐ *Physician Referrals*
☐ *Clinic*
☐ *Calls to CIS*
☐ *Advertising*
☐ *Website*
☒ *Other (explain)*
Recruitment through Urology department when scheduled for RALP procedure

Signature of PI: ____Kimberly A. Davis, DrNP(c), CRNA_____ ***Date***: 12/12/13

Checklist to Include with this Form:
X Application for Continuing Review (including Review Request, Activity Report and Reviewer Evaluation, one copy of newest protocol including all changes)
X Electronic Copy of currently approved Informed Consent Document/HIPAA
N/A Data Safety Monitoring Report (if applicable)

Appendix H (continued)

IRB #11-883

Review Request

Study Objectives:	==ACCRUAL==		
———		Projected	Actual
	Total (All Sites)	46	48
	Total (FCCC & Network)	46	48
	Total (FCCC Only)	46	48
	Annual *(FCCC Only)		
	Months active overall	1-3	5
	Months active from last IRB	2	2
	Withdrawals**	0	0
	*Note: Actual annual accrual tabulated from last IRB review date **If applicable list reasons for withdrawal on activity report		

Comments:
- ☒ There are no additional treatment-related toxicities or safety issues with an impact on study
- ☐ Additional treatment-related toxicities and/or safety issues are attached.
- ☐ Protocol and/or informed consent changes are attached.
- ☐ This is an NCI-sponsored national cooperative group trial with anticipated low accrual. Prioritization is reviewed at semi-annual group meetings.

Protocol data reviewed by: Kimberly A. Davis Print Name: Kimberly A. Davis

PI Request:
- ☐ Renew for active patient accrual.
- ☐ Study is currently suspended, renew for patient accrual if re-activated by sponsor.
- ☒ Renew. Study is closed to new accrual but remains active for treatment and/or follow-up of enrolled participants or data analysis - continuing review required.
- ☐ Study approved but not yet activated – continuing review required.
- ☐ Do not renew. Protocol terminated.

Principal Investigator: Kimberly A. Davis, DrNP(c), CRNA Print Name: Kimberly A. Davis, DrNP(c), CRNA

DO NOT WRITE BELOW THIS LINE

RRC Action:		IRB Action:
	Approved for active patient accrual (12 months)	Approved for active patient accrual (12 months)
	Approved for active patient accrual (6 months) with warning	Approved for active patient accrual (6 months) with warning
Y	Approved for continuing patient evaluation, closed to active accrual	Approved for continuing patient evaluation, no active accrual
	Approved for continuing review but not yet opened	Approved for continuing review but not yet opened
	Protocol terminated	Protocol terminated
	Tabled pending investigator response	Tabled pending investigator response

Chairperson: _____ Chairperson: _____

Date: 12-9-13 Date: 1/10/14

Appendix H (continued)

IRB #11-883

Activity Report

Review/Approval and Activity* [1]

Date	*Activity**	*Comments*

*Activities include amendments, withdrawals[1] and reasons, adverse events, unanticipated problems or outcomes, changes to the consent form, suspensions, closures and terminations.

[1] Include subjects withdrawn from the study or been withdrawn from the study by the investigator

USE ADDITIONAL PAGES AS NECESSARY

Appendix H (continued)

IRB #11-883

Summary of Accrual (FCCC Only)

*Subject ID***	*Sex*	*Race*	*Start Date End Date*	*Date of Death*

**Subject ID should be a code, rather than subject identifiable information.

USE ADDITIONAL PAGES AS NECESSARY

Appendix H (continued)

FOX CHASE CANCER CENTER
TEMPLE HEALTH

Institutional Review Board
Federal Wide Assurance #00003846

APPROVAL OF PROTOCOL

January 24, 2014

Kimberly Davis, DrNP, CRNP

Dear Kimberly:

On January 10, 2014 the IRB reviewed the following protocol:

Type of Review:	Continuing
Title:	Pain Management and Comfort in Robotic Laparoscopic Prostatectomy Patients
Investigator:	Kimberly Davis, DrNP, CRNP
IRB ID:	11-883
Funding:	Fox Chase Cancer Center
Grant Title:	None
Grant ID:	None
IND, IDE or HDE:	None
Documents Reviewed:	Continuing Review Application Protocol Version 2.0 dated 06/06/2012

- Upon review, the submission meets the criteria for the approval of research outlined in 45 CFR 46.111.
- The IRB approved the protocol from January 10, 2014 to January 09, 2015 inclusive. Before January 09, 2015 or within 30 days of final study close-out, whichever is earlier, you are to submit a completed Continuing Review Progress Report and required attachments to request continuing approval or final study close-out (termination).
- If continuing review approval is not granted before the expiration date of January 09, 2015 approval of this protocol expires on that date.

Sincerely,

IRB Vice-Chairperson/Eric Tetzlaff, PA-C

Appendix H (continued)

IRB #11-883

**********DO NOT WRITE BELOW THIS LINE********FOR IRB USE ONLY **********

Regulatory Review Requirement	Reviewed	Suggested Questions for IRB
Risk to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may be reasonably expected to result.	Y	
Frequency and extent of continuing review.	365	Is there sufficient risk to warrant review of this protocol sooner than the standard 365 days?
Confirmation of use of approved protocol.	Y	Have all changes in the protocol to be reviewed already been reviewed and approved by the IRB?
Confirmation of use of approved consent form.		Is the consent form appropriately reflective of the protocol? Is there a need to request confirmation from someone other than the PI that no changes have been made to the protocol other than those previously reviewed and approved by the IRB? Is the current consent still accurate and complete?
Review of progress of the study.	Y	What progress has been made? What changes to the protocol have been necessitated? What have been the experiences of the subjects (adverse events and benefits)?
Confirmation that the study is conducted in accordance with appropriate guidelines and regulations.	Y	Is this study being conducted in accordance with IRB policies and procedures?
Discussion of findings to date of this study or existing literature.	NA	Has any new information been discovered that may affect a subject's decision to participate or continue to participate? If so, how has this information been communicated to currently accrued subjects?
Terminated study review and notification of subjects.	NA	Have all subjects been notified that the study has been terminated? If so, by what method?

Risk/Benefit Assessment

RISK

Regulatory definition of minimal risk: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(h)(1)).

Check appropriate risk category:

1. __X__ The research involves no more than minimal risk to subjects.
2. _____ The research involves more than minimal risk to subjects.
   a. _____ The risk(s) represents a minor increase over minimal risk, **or**
   b. _____ The risk(s) represents more than a minor increase over minimal risk.

BENEFIT

Definition: A research benefit is considered to be something of health-related, psychosocial, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participation in research is not considered to be a benefit, but rather compensation for research-related inconveniences.

Check appropriate benefit category:

1. __X__ The research involves no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition.
2. _____ The research involves the prospect of direct benefit to individual subjects.

*I verify that the regulatory criteria for approval of research have been met.

Reviewer Name: ERIC TEPLICS *Signature: [signature]

Continuing Review Application
Version 02/2013

Page 6 of 6

Appendix H (continued)

IRB #11-883

**********DO NOT WRITE BELOW THIS LINE********FOR IRB USE ONLY **********

Regulatory Review Requirement	Reviewed	Suggested Questions for IRB
Risk to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may be reasonably expected to result.	Y	
Frequency and extent of continuing review.	365	Is there sufficient risk to warrant review of this protocol sooner than the standard 365 days?
Confirmation of use of approved protocol.	Y	Have all changes in the protocol to be reviewed already been reviewed and approved by the IRB?
Confirmation of use of approved consent form.		Is the consent form appropriately reflective of the protocol? Is there a need to request confirmation from someone other than the PI that no changes have been made to the protocol other than those previously reviewed and approved by the IRB? Is the current consent still accurate and complete?
Review of progress of the study.	Y	What progress has been made? What changes to the protocol have been necessitated? What have been the experiences of the subjects (adverse events and benefits)?
Confirmation that the study is conducted in accordance with appropriate guidelines and regulations.	Y	Is this study being conducted in accordance with IRB policies and procedures?
Discussion of findings to date of this study or existing literature.	NA	Has any new information been discovered that may affect a subject's decision to participate or continue to participate? If so, how has this information been communicated to currently accrued subjects?
Terminated study review and notification of subjects.	NA	Have all subjects been notified that the study has been terminated? If so, by what method?

Risk/Benefit Assessment

RISK

Regulatory definition of minimal risk: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(h)(1)).

Check appropriate risk category:

1. Y The research involves no more than minimal risk to subjects.
2. _____ The research involves more than minimal risk to subjects.
   a. _____ The risk(s) represents a minor increase over minimal risk, **or**
   b. _____ The risk(s) represents more than a minor increase over minimal risk.

BENEFIT

Definition: A research benefit is considered to be something of health-related, psychosocial, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participation in research is not considered to be a benefit, but rather compensation for research-related inconveniences.

Check appropriate benefit category:

1. NO The research involves no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition.
2. _____ The research involves the prospect of direct benefit to individual subjects.

*I verify that the regulatory criteria for approval of research have been met.

Reviewer Name: ERIC TERRACE *Signature: [signature]

Continuing Review Application
Version 02/2013

Page 6 of 6

Appendix I

Updated Consent with  **Temple Logo**

INFORMED CONSENT DOCUMENT

Pain Management and Comfort in Robotic Laparoscopic Prostatectomy Patients

Principal Investigator: Kimberly A. Davis, DrNP(c) CRNA

This is a research study. Your study nurse will explain the study to you. Research studies include only people who choose to take part. Please take your time to make your decision about taking part. You should discuss your decision with your friends and family. You will also discuss it with your health care team. If you have any questions, you can ask your study nurse for more explanation.

You are being asked to take part in this research study because you have Prostate Cancer and have chosen Robotic Laparoscopic Prostatectomy surgery.

The sponsor of this study is Fox Chase Cancer Center.

Why is this research study being done?

The purpose of this study is to find out the best pain management strategy for Robotic Laparoscopic Prostatectomy surgery. We would like to find out what combination of medications works best after this surgery. Ultimately, we would like to develop a “best practice” pain management strategy to address the needs of patients who undergo this surgery.

You will receive the same care and medications chosen by your anesthesia provider whether or not you participate in this study. These medications will be reviewed after your surgery is complete and compared to your pain score (your nurse will ask you to rate your pain as a part of your care). We do not know if you will benefit from this research study. We can use what we learn from this research study to help other people with the same disease who undergo the same surgery.

How many people will take part in this research study?

About 23 people for each group (two groups) will be needed for this research. A total of 46 people will take part in this research study if able to fill groups evenly.

Appendix I (continued)

What will happen if you take part in this research study?

Questionnaires
Before you begin the study, we will ask you to fill out a Demographic Data Form which is a Questionnaire that will be filled out one time only and takes less than 5 minutes for completion.

Prior to surgery, The Numerical Pain Intensity Scale (NRS) and Comfort Questionnaire will be completed. These questionnaires will tell us about your pain and your comfort. It will take approximately 10-15 minutes to complete the Comfort Questionnaire. We will ask you to fill this out before your surgery one time and one time after your surgery for a total of two times (and 30 minutes) during this research study.

You do not have to answer any questions that make you uneasy. Whether or not you answer any question will not affect your medical care. We will keep the paper copies of the questionnaires in a locked file to protect your privacy.

No tests or procedures will be required to participate in this study.

Medication Review for group placement – You will not be required to do anything. Medications you had during surgery will be reviewed.

Study Chart

You will receive **a questionnaire** one time before your surgery and one time after your surgery describing your comfort for this research study. This [two questionnaires from before your surgery until you return to your room] is called a cycle in the research time frame. The cycle will not be repeated. The chart below shows what will happen to you during your participation in this research. The left-hand column shows the day in the cycle and the right-hand column tells you what to do on that day.

Cycle 1 – There is only one cycle

Day	What you do
Prior to Surgery Admission	Fill out Demographic Data Sheet, Numeric Pain Intensity Scale for Pain & General Comfort Questionnaire (16-21 minutes total time).
Day of Surgery	Report for Surgery, Fill out Numeric Pain Intensity Scale (1 minute total time).
Recovery Room	Numeric Pain Intensity Scale (1 minute total time) completed in PACU.
Admission to Room	Numeric Pain Intensity Scale & General Comfort Questionnaire (11-16 minutes total time).
Research after Admission to Room	Researcher will Review Data for Medications Received & gather information Numeric Pain Intensity Scale from medical record.
Conclusion	No further information or Questionnaires Required.

Appendix I (continued)

How long will you be in the research study?

The research study will be complete after you have been admitted to your room after your surgery and have completed the final Numeric Pain Intensity Scale & General Comfort Questionnaire. Since there is no change in your care during this research, no follow up will be required. You will continue follow up with your surgeon as directed.

Can you stop being in the research study?

Yes. You can decide to stop at any time. Tell the study coordinator if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study coordinator if you are thinking about stopping so any risks can be evaluated as needed. Another reason to tell your research coordinator that you are thinking about stopping is to discuss what followup care could be most helpful for you.

Can you be removed from this research study?

The study nurse may stop you from taking part in this research study at any time if he/she believes it is in your best interest; if you do not follow the research study rules; or if the research study is stopped.

What side effects or risks can you expect from being in the research study?

The study involves little risk for participants. Your medical record review will reveal which group you will be placed into only after your care is complete. You will not receive any specific medications while taking part in this research. You will not require any blood work or testing as a result of participation in this research. You should talk to your study nurse about any issues that you may have while taking part in the research study.

There may be a possible risk of negative feelings after you complete the General Comfort Questionnaire. You should talk to your study nurse about any issues that you may have while taking part in the research study.

Are there benefits to taking part in the study?

Taking part in this study may or may not make your health better. While your healthcare providers administer high quality care with monitored comfort and pain control, it would be more useful to compare the variety of treatment modalities. This study may provide information to help us determine the best pain management strategy for the robotic laparoscopic procedure. An improved pain management strategy may improve pain control and comfort for a quick recovery, and it may also result in expedited discharge from the hospital. Although there is no proof of this yet, we do know that the information from this study will help your healthcare team learn more about improving pain control and comfort for this specific type of surgery. This information could help future cancer patients.

Appendix I (continued)

What other choices do you have if you do not take part in this research study?
Your other choices may include:

- Getting treatment or care for your cancer without being in a study
- Taking part in another study
- Getting no treatment

Talk to your doctor about your choices before you decide if you will take part in this study.

Will your medical information be kept private?
We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- Fox Chase Cancer Center, Institutional Review Board
- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people

You will be given a separate form to review regarding the steps we will take to guard your privacy as part of your participation in the research study. By signing that additional authorization, you will be providing your consent to use and disclose information described in that form connected with your participation in this research study.

What are the costs?
Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

Will you be compensated?
You will not get paid for taking part in this research study. If you are harmed because of the research study, we will provide the medical care to treat that harm. However, you may have to pay for this treatment. Fox Chase Cancer Center has not set aside funds to pay your salary if you cannot work or for any other damages if you are harmed because of the research study.

What are your rights if you take part in this research study?
Taking part in this research study is your choice. You may choose either to take part or not to take part in the research study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.
In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Appendix I (continued)

New findings
We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

Who can answer your questions about the research study?

If you have questions about:	Please Page:
This study	Kimberly A. Davis, DrNP(c), CRNA 215-308-1262
If you get sick or hurt in this study	Kimberly A. Davis, DrNP(c), CRNA 215-308-1262
If you have a concern or complaint	Director, Risk Management 215-728-2591
Your rights as a research participant while you are on this study or after the study ends	Institutional Review Board 215-214-3754
Your bills or health insurance coverage	Clinical Trial Financial Counselor 215-214-3768

Where can you get more information?
You may call the National Cancer Institute's Cancer Information Service at:
1-800-4-CANCER (1-800-422-6237)

- You may also visit the NCI website at http://cancer.gov
- For NCI's clinical trials information, go to: http://cancer.govclinicaltrials/
- For NCI's general information about cancer, go to: http://cancer.gov/cancerinfo/

By signing below, you tell us that you have gotten all of the information you need; that you have received clear answers to your questions, and that you agree to take part in the research study. You will receive a copy of this form. You may also request a copy of the research plan.

Signature of Participant	**Print Name of Participant**	**Date**
Signature of Person Obtaining Consent	**Print Name of Person Obtaining Consent**	**Date**

By signing this form the Physician obtaining consent indicates that the research participant has been fully informed of all aspects of the research study.

Appendix J

Updated HIPPA with  Temple Logo

Authorization (Permission) to Use or Disclose (Release) Protected Health Information (PHI) for Research

IRB# and Protocol ID:	IRB #11-883
Study Title:	Pain Management and Comfort in Robotic Laparoscopic Prostatectomy Patients
Principal Investigator:	Kimberly A. Davis, DrNP(c), CRNA
Coordinating Group (or Center):	Fox Chase Cancer Center
Other Sponsor(s):	

3. What is the purpose of this form?

This form is required by the Health Insurance Portability and Accountability Act of 1996. Specifically the privacy regulation (HIPAA) permits the research investigators listed above to use and disclose health information about you for the research study identified above which has been approved by the Fox Chase Cancer Center Institutional Review Board.

The Fox Chase Cancer Center is an organization that does research to learn about the causes of cancer, and how to prevent and treat cancer. Researchers would like to use your protected health information for research. The elements of protected health information as defined by HIPAA are:

Data Elements for Protected Health Information (PHI)

- Names
- All geographic subdivisions smaller than a state (except for the first 3 digits of the zip code in some cases)
- All elements of dates (except year) for dates directly related to an individual (e.g., birth date, admission date, discharge date, date of death) and all ages over age 89 and dates indicative of that age
- Telephone numbers
- Fax numbers
- E-mail addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URL)
- Internet Protocol (IP) addresses
- Biometric identifiers, including finger and voice prints

Appendix J (continued)

- Full face photos and any comparable images
- Any other unique identifying number, characteristic, or code

2. What protected health information do the researchers want to use?

The researchers may want to copy and use the portions of your health information that they will need for their research. If you enter a research study, health information that maybe used and/or released include the following:

- Personal medical history;
- Family medical history;
- Tissue/blood/cells/DNA;
- Content of audio/video recording of sessions;
- Current and past cancer screening and lifestyle practices, medications, therapies, diagnostic tests, surgeries, and/or biopsies;
- Information from a genetic test you may have had in the past (for example, BRCA1 and/or BRCA2 testing)
- Any information collected in the Health History Questionnaire and/or other survey instruments completed during the course of the study.

You may request a blank copy of the data forms from the study doctor or his/her research staff to learn what information will be shared.

3. Why do the researchers want my protected health information?

Fox Chase Cancer Center will collect your protected health information and share it with the Fox Chase Cancer Center Biostatistical Center if you enter a research study. The center will use your information in their cancer research study.

4. Who will be able to use my protected health information?

Fox Chase Cancer Center will use your health information for research. As part of this research, it may give your information to the following groups taking part in the research. Fox Chase Cancer Center may also permit these groups to come in to review your original records that are kept by Fox Chase Cancer Center so that they can monitor the research study.

- The Fox Chase Cancer Center Biostatistical Center
- Public health agencies and other government agencies (including non-U.S.) as authorized or required by law;
- Other people or organizations assisting with research efforts of the Fox Chase Cancer Center

5. How will information about me be kept private?

Fox Chase Cancer Center will keep all health information private to the extent possible. Only researchers working with Fox Chase Cancer Center or the sponsor will have access to your information. Fox Chase Cancer Center or the sponsor will not release personal health information about you to others except as authorized or required by law. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

Appendix J (continued)

6. What happens if I do not sign this permission form?

If you do not sign this permission form, you will not be able to take part in the research study for which you are being considered.

7. If I sign this form, will I automatically be entered into the research study?

No, you cannot be entered into any research study without further discussion and separate consent. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a specific research consent form.

Treatment by your physician will not be affected by whether you provide authorization for the requested use or disclosure except if your treatment is related to research.

8. What happens if I want to withdraw my permission?

You can change your mind at any time and withdraw your permission to allow your protected health information to be used in the research. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new protected health information will be used for research. However, researchers may continue to use the protected health information that was provided before you withdrew your permission. If you sign this form and enter the research study, but later change your mind and withdraw your permission, you will be removed from the research study at that time.

To withdraw your permission, please contact the person below. She will make sure your written request to withdraw your permission is processed correctly.

Contact Name:	Kimberly A. Davis, DrNP(c), CRNA
Contact Address:	333 Cottman Avenue, Philadelphia, PA
Contact Phone and FAX:	Pager, 215 308 1262; Phone 215 728 3180; FAX 215 214 1734

9. How long will this permission last?

If you agree by signing this form that researchers can use your protected health information, this permission has no expiration date. However, as stated above, you can change your mind and withdraw your permission at any time.

10. What are my rights regarding access to my personal health information?

You have the right to refuse to sign this permission form. You have the right to review and/or copy records of your protected health information kept by Fox Chase Cancer Center.

****

S*Signatures*

I agree that my protected health information may be used for the research purposes described in this form.

Participant Signature: _____ Date: _____

or Legal Representative: _____ Date: _____

Printed Name of Legal Representative (if any): _____

****

Appendix J (continued)

FOX CHASE CANCER CENTER
TEMPLE HEALTH

Appendix J

INFORMED CONSENT DOCUMENT

Pain Management and Comfort in Robotic Laparoscopic Prostatectomy Patients

Principal Investigator: Kimberly A. Davis, DrNP(c) CRNA

This is a research study. Your study nurse will explain the study to you. Research studies include only people who choose to take part. Please take your time to make your decision about taking part. You should discuss your decision with your friends and family. You will also discuss it with your health care team. If you have any questions, you can ask your study nurse for more explanation.

You are being asked to take part in this research study because you have Prostate Cancer and have chosen Robotic Laparoscopic Prostatectomy surgery.

The sponsor of this study is Fox Chase Cancer Center.

Why is this research study being done?

The purpose of this study is to find out the best pain management strategy for Robotic Laparoscopic Prostatectomy surgery. We would like to find out what combination of medications works best after this surgery. Ultimately, we would like to develop a "best practice" pain management strategy to address the needs of patients who undergo this surgery.

You will receive the same care and medications chosen by your anesthesia provider whether or not you participate in this study. These medications will be reviewed after your surgery is complete and compared to your pain score (your nurse will ask you to rate your pain as a part of your care). We do not know if you will benefit from this research study. We can use what we learn from this research study to help other people with the same disease who undergo the same surgery.

How many people will take part in this research study?

About 23 people for each group (two groups) will be needed for this research. A total of 46 people will take part in this research study if able to fill groups evenly.

What will happen if you take part in this research study?

Questionnaires
Before you begin the study, we will ask you to fill out a Demographic Data Form which is a Questionnaire that will be filled out one time only and takes less than 5 minutes for completion.

Appendix J (continued)

Prior to surgery, The Numerical Pain Intensity Scale (NRS) and Comfort Questionnaire will be completed. These questionnaires will tell us about your pain and your comfort. It will take approximately 10-15 minutes to complete the Comfort Questionnaire. We will ask you to fill this out before your surgery one time and one time after your surgery for a total of two times (and 30 minutes) during this research study.
You do not have to answer any questions that make you uneasy. Whether or not you answer any question will not affect your medical care. We will keep the paper copies of the questionnaires in a locked file to protect your privacy.
No tests or procedures will be required to participate in this study.

Medication Review for group placement – You will not be required to do anything. Medications you had during surgery will be reviewed.

Study Chart

You will receive **a questionnaire** one time before your surgery and one time after your surgery describing your comfort for this research study. This [two questionnaires from before your surgery until you return to your room] is called a cycle in the research time frame. The cycle will not be repeated. The chart below shows what will happen to you during your participation in this research. The left-hand column shows the day in the cycle and the right-hand column tells you what to do on that day.

Appendix J (continued)

Cycle 1 – There is only one cycle

Day	What you do
Prior to Surgery Admission	• Fill out Demographic Data Sheet, Numeric Pain Intensity Scale for Pain & General Comfort Questionnaire (16-21 minutes total time).
Day of Surgery	• Report for Surgery, Fill out Numeric Pain Intensity Scale (1 minute total time).
Recovery Room	• Numeric Pain Intensity Scale (1 minute total time) completed in PACU.
Admission to Room	• Numeric Pain Intensity Scale & General Comfort Questionnaire (11-16 minutes total time).
Research after Admission to Room	• Researcher will Review Data for Medications Received & gather information Numeric Pain Intensity Scale from medical record.
Conclusion	• No further information or Questionnaires Required.

How long will you be in the research study?

The research study will be complete after you have been admitted to your room after your surgery and have completed the final Numeric Pain Intensity Scale & General Comfort Questionnaire. Since there is no change in your care during this research, no follow up will be required. You will continue follow up with your surgeon as directed.

Can you stop being in the research study?

Yes. You can decide to stop at any time. Tell the study coordinator if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study coordinator if you are thinking about stopping so any risks can be evaluated as needed. Another reason to tell your research coordinator that you are thinking about stopping is to discuss what followup care could be most helpful for you.

Appendix J (continued)

Can you be removed from this research study?
The study nurse may stop you from taking part in this research study at any time if he/she believes it is in your best interest; if you do not follow the research study rules; or if the research study is stopped.

What side effects or risks can you expect from being in the research study?
The study involves little risk for participants. Your medical record review will reveal which group you will be placed into only after your care is complete. You will not receive any specific medications while taking part in this research. You will not require any blood work or testing as a result of participation in this research. You should talk to your study nurse about any issues that you may have while taking part in the research study.

There may be a possible risk of negative feelings after you complete the General Comfort Questionnaire. You should talk to your study nurse about any issues that you may have while taking part in the research study.

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Taking part in this study may or may not make your health better. While your healthcare providers administer high quality care with monitored comfort and pain control, it would be more useful to compare the variety of treatment modalities. This study may provide information to help us determine the best pain management strategy for the robotic laparoscopic procedure. An improved pain management strategy may improve pain control and comfort for a quick recovery, and it may also result in expedited discharge from the hospital. Although there is no proof of this yet, we do know that the information from this study will help your healthcare team learn more about improving pain control and comfort for this specific type of surgery. This information could help future cancer patients.

What other choices do you have if you do not take part in this research study?

Your other choices may include:
- Getting treatment or care for your cancer without being in a study
- Taking part in another study
- Getting no treatment

Talk to your doctor about your choices before you decide if you will take part in this study.

Appendix J (continued)

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- Fox Chase Cancer Center, Institutional Review Board
- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people

You will be given a separate form to review regarding the steps we will take to guard your privacy as part of your participation in the research study. By signing that additional authorization, you will be providing your consent to use and disclose information described in that form connected with your participation in this research study.

What are the costs?

Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

Will you be compensated?

You will not get paid for taking part in this research study. If you are harmed because of the research study, we will provide the medical care to treat that harm. However, you may have to pay for this treatment. Fox Chase Cancer Center has not set aside funds to pay your salary if you cannot work or for any other damages if you are harmed because of the research study.

What are your rights if you take part in this research study?

Taking part in this research study is your choice. You may choose either to take part or not to take part in the research study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Appendix J (continued)

New findings

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

Who can answer your questions about the research study?

If you have questions about:	Please Page:
This study	Kimberly A. Davis, DrNP(c), CRNA 215-308-1262
If you get sick or hurt in this study	Kimberly A. Davis, DrNP(c), CRNA 215-308-1262
If you have a concern or complaint	Director, Risk Management 215-728-2591
Your rights as a research participant while you are on this study or after the study ends	Institutional Review Board 215-214-3754
Your bills or health insurance coverage	Clinical Trial Financial Counselor 215-214-1727

Where can you get more information?
You may call the National Cancer Institute's Cancer Information Service at:

1-800-4-CANCER (1-800-422-6237)

- You may also visit the NCI website at http://cancer.gov
- For NCI's clinical trials information, go to: http://cancer.govclinicaltrials/
- For NCI's general information about cancer, go to: http://cancer.gov/cancerinfo/

By signing below, you tell us that you have gotten all of the information you need; that you have received clear answers to your questions, and that you agree to take part in the research study. You will receive a copy of this form. You may also request a copy of the research plan.

Signature of Participant	**Print Name of Participant**	**Date**
Signature of Person Obtaining Consent	**Print Name of Person Obtaining Consent**	**Date**

By signing this form the Physician obtaining consent indicates that the research participant has been fully informed of all aspects of the research study.

Appendix K

TITLE: Pain Management and Comfort in Robotic Laparoscopic Prostatectomy Patients

PRINCIPAL INVESTIGATOR:
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Version 1.0 – 01/27/2012
Version 2.0 – 06/06/2012
Version 3.0 – 3/17/2014

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INFORMED CONSENT

APPENDIX

Demographic Data Sheet

General Comfort Questionnaire

Numeric Rating Scale 0-10 Pain Scale

Appendix K (continued)

1.0 SCHEMA

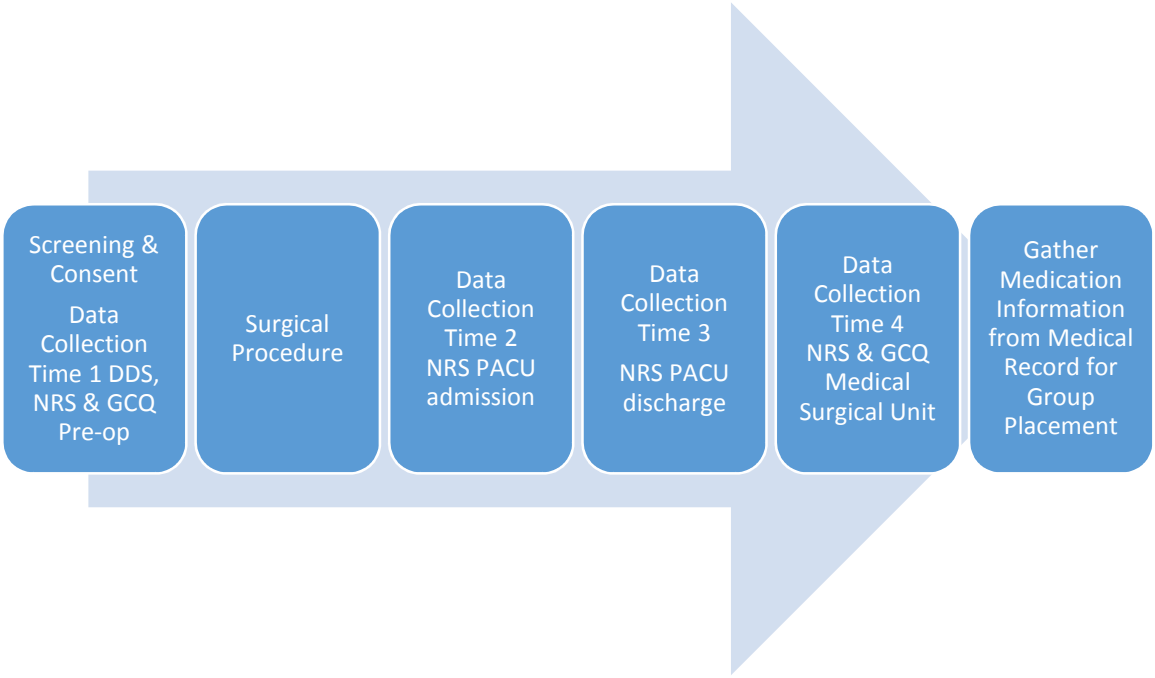
Inclusion Criteria:

1. Adult Male subjects age 18 and older
2. Those who are scheduled for RALP*
3. Willing to participate in study
4. Anesthesia standard of care includes opioids with or without α 2 agonist

Exclusion Criteria:

1. Dependent upon others to make health care decisions
2. If anesthetic/surgical event in which participant is unable to complete pain and comfort scale or conversion of RALP procedure to open radical prostatectomy
3. Applicable group at required statistical participant level
4. No Opioids used

*RALP = Robotic Assisted Laparoscopic Prostatectomy



Appendix K (continued)

2.0 OBJECTIVES

The ***purpose*** of this study is to determine the best pain management strategy for this robotic laparoscopic procedure, both improving pain control and comfort for a facilitated recovery and expedited discharge from the hospital. A procedure specific approach to peri-operative pain management is appropriate to optimize multimodal pain management strategies (White & Kehlet, 2010).

The ***long-term goal*** of this project therefore is to develop a best practice pain management strategy to address the needs of Robotic Assisted Laparoscopic Prostatectomy (RALP) patients' through improvement of comfort and pain control. The ***objective*** of this study is to identify the relationship of pain management to comfort in this robotic surgical population through comparison of two standards of anesthesia care protocol in the peri-operative setting.

The specific aims of this project are:

1. **Compare the effect of 2 pharmaceutical regimens on pain and comfort in the laparoscopic robotic prostatectomy patient.** The null hypothesis: There will be no difference between two standard anesthesia protocols with regard to pain and comfort prior to surgery, admission to PACU after surgery, discharge from PACU, and admission to the Surgical Unit.
2. **Explore the relationship between pain and comfort in post-operative RALP patients.** The null hypothesis: Decreased pain will not be associated with increased comfort.

3.0 BACKGROUND

Pain assessment and management has become a priority to many stakeholders including medical caregivers, patients, health care organizations and credentialing agencies. "Pain is whatever the experiencing person says it is, existing whenever the experiencing person says it does (McCaffery & Beebe, 1989, p. 7)." The Joint Commission (**TJC**) in 2000 began including pain control as a part of the national standards and accreditation process (TJC, 2009). California has passed regulations regarding pain as the 5th vial sign (State of California Department of Consumer Affairs, 2000) and the Veterans Administration published a 57 page toolkit implementing a Veteran Health Administration (VHA) National Pain Management Strategy to promote pain as the 5th vital sign and offer **guidelines for comprehensive pain assessment** (Department of Veteran Affairs, 2000). Further, pain plays a significant role in consumer satisfaction. Consumer satisfaction is a growing interest which is important to all stakeholders, including health care providers. Consumers satisfaction with care related to pain and comfort have been shown to be highly correlated to scores on the Hospital Consumer Assessment of Healthcare Providers and Systems (**HCAHPS**) survey with a Cronbach's alpha, 0.94, and correlation coefficient 0.84 for communication and adequate pain control (Jha, Orav, Zheng & Epstein, 2008).

Appendix K (continued)

Wilson and Kolcaba (2004), describe a comfort theory relating to nursing which depicts the importance for enhanced comfort in patients. Comfort has many meanings and connotations; it is much more than ease or relief of discomfort. Holistic comfort may include physical, psychospiritual, sociocultural, and environmental needs (Wilson & Kolcaba). Comfort is defined as "the immediate state of being strengthened through having the human needs for relief, ease, and transcendence (types of comfort) addressed physically, psychospiritually, socioculturally, and environmentally (contexts in which comfort is experienced) (Kolcaba, 2003, p. 251)."

Although pain is reduced in minimally invasive surgery, there is a ***gap*** in the literature describing **pain and comfort management** with **therapeutic regimens**. Therapeutic regimens are recommended plans of care. This may be a protocol for pain management, such as specific groups of medications found to be most effective for care during surgery. A wide array of pharmacologic agents may be used independently or combined for pain control and comfort. Variation of pharmacologic selections may be practitioner dependent. Optimizing pain control and comfort levels are key issues important in facilitating a rapid recovery and patient discharge.

Seventy five million Americans suffer from serious or severe pain and 50 million of those people endure chronic daily pain serious enough to affect their quality of life (Yass, 2009). The American Pain Society has created a mission to serve people in pain through advancing research, education, treatment, and professional practice. The under treatment of pain in today's society is not justified. With a growing trend toward laparoscopic procedures, specifically robotic laparoscopic; it is important to determine the **effectiveness of pain and comfort in the peri-operative period**. Pain management and comfort are important goals to achieve in order to facilitate and improve patient care and outcomes.

Pain control modalities and treatments in this research proposal focus specifically on pharmacologic modalities.

Opioid Sparing

Opioid sparing is a modality used to reduce side effects of medications. A non-opioid medication used in combination with opioids to reduce opioid requirements is termed opioid-sparing. Significant side effects of opioids can interfere with recovery and reduce a patient's comfort level (Kehlet, 2005). Using opioid dose sparing strategies assists in alleviating harsh side effects (Wheeler, Oderda, Ashburn & Lipman, 2002). Multimodal balanced analgesia applies the opioid sparing technique leading to a reduction in adverse effects of opioids (Kehlet). The Joint Commission has set a standard for pain management to reduce patients' pain (Kehlet). If this goal is achieved though opioids alone, there is an increased risk of adverse effects (Kehlet). Although the National Institute of Health (NIH) practice guidelines suggest opioids be the primary mode of analgesia, concerns related to adverse effects are significant (Wheeler, Oderda, Ashburn & Lipman). Many studies have shown the benefits of multimodal analgesia with a variety of differing cases; however; there is limited information on this approach after robotic surgery.

Appendix K (continued)

Multimodal Analgesia

Multimodal analgesia a modality used to reduce side effects of medications. Multimodal balanced analgesia can help to reduce adverse outcomes generally associated with opioids alone. Rationale for multimodal analgesia is to reduce the dose of each analgesic which improves anti-nocioception due to synergistic or additive effects; this may reduce the severity of side effects (Kehlet & Dahl, 1993). The goal of multimodal analgesia is opioid sparing which reduces postoperative morbidity and medication related complications (White, Kehlet & Liu, 2009; Classen, 1997). Combining analgesics from differing drug classes improves safety and efficacy through the variety of each drugs mechanism of action (White & Kehlet, 2010).

Pharmacologic Agents

A variety of medications may provide postoperative analgesia. Analgesia is defined as the insensibility of pain without loss of consciousness (analgesia, 2010). Many different combinations of pharmacologic agents may be used to produce analgesia, including local anesthetics, opioids, and alpha-2 agonists. Dexmedetomidine is an alpha-2 adrenergic agonist which provides sedation while decreasing anesthetic use without respiratory depression (Davis, Waters, Vinson, Eddy & Vick, 2000). Although opioids reduce pain, side effects associated with these agents may contribute to discomfort (Wu, et al., 2005). Further, use of local anesthetics at port and incision sites can improve patients' pain and comfort, and further reduce opioid requirements.

The two standards of care anesthetic regimens proposed for this research will provide further information on both the multimodal balanced analgesia and opioids alone approach to pain management. Further identification of single agent pain control compared to two agents will guide our practice to the best pain management strategy for this robotic laparoscopic procedure. Therefore the two protocol groups will be those participants who received opioids alone and those who received opioids with an α 2 agonist.

As the use of **robotics continues to grow and diversify**, new criteria come to light with a focus on pain control, reducing invasiveness and promoting early discharge. A variety of pharmacologic agents have been used to treat pain and improve comfort in this population. Each patient may have more than one analgesic agent which may be termed "multimodal therapy". Multimodal therapy combines analgesics with differing mechanisms of action to create a synergistic effect, thereby reducing total doses of each drug (Kamming, Chung, Williams, McGrath & Curti, 2004). This method allows a reduction of opioid requirements and the side effects frequently associated with them (Kamming, et. al.). Analgesia protocols may assist in reducing variance of practice and improve pain management (Kamming, et. al.). The ***purpose*** of this study is to determine the best pain management strategy for this robotic laparoscopic procedure, both improving pain control and comfort for a facilitated recovery and expedited discharge from the hospital. A procedure specific approach to peri-operative pain management is appropriate to optimize multimodal pain management strategies (White & Kehlet, 2010).

Appendix K (continued)

This study will provide a scientific base for development of improved pharmacologic pain and comfort interventions. Pain and comfort in this relatively new procedure has not been adequately addressed. This study will provide important information about the efficacy of pain management in the immediate postoperative period by comparing two anesthetic regimens. The results could be used to guide future anesthetic practice.

Kimberly A. Davis, DrNP(c), CRNA is a candidate for Drexel University Doctoral Nursing Research Program and this research is required for program completion. Doctoral Candidate Davis has been a practicing RN for 22 years and CRNA for 11 of those years. Her interest in pain management led her to a career in Anesthesia and her Doctoral work is focused on this area combining minimally invasive procedures and pain management strategies. A consultation with Dr. Andrea Barsevick provided further insight into research development at Fox Chase Cancer Center. The entire Urology Team at Fox Chase Cancer Center is Co-Investigators and Dr. Fang Zhu will provide statistical analysis and support throughout the proposal and research.

4.0 STUDY DESIGN

This proposal is an Observational Descriptive Study with No Intervention. The research study is a prospective quantitative study with a convenience sample. This will be a cross sectional study controlling for procedure type. Groups will be defined after treatment is complete, ensuring no manipulation of plan of care or treatment strategy. A retrospective chart review will be used to determine group placement of participants: Group A or Group B.

5.0 PATIENT SELECTION

A convenience sample from a Philadelphia institution will provide recruitment of subject pool. Fox Chase Cancer Center is located in Northeast Philadelphia, PA.

Inclusion Criteria:

1. Adult Male subjects age 18 and older
2. Those who are scheduled for RALP
3. Willing to participate in study
4. Anesthesia standard of care includes opioids with or without α 2 agonist

Exclusion Criteria:

1. Dependent upon others to make health care decisions
2. If anesthetic/surgical event in which participant is unable to complete pain and comfort scale or conversion of RALP procedure to open radical prostatectomy
3. Applicable group at required statistical participant level
4. No Opioids used

*RALP = Robotic Assisted Laparoscopic Prostatectomy

Appendix K (continued)

6.0 SURVEY PROCEDURES

The Primary Investigator (PI) Kimberly Davis, will be project staff. Fox Chase Cancer Center RRC & IRB review of Proposed Research. Drexel University RRC & IRB review of Proposed Research. Once approved by both Fox Chase Cancer Center & Drexel University, begin research study. Individuals scheduled for RALP at Fox Chase Cancer Center will be potential participants for this study. All adult males who meet the inclusion criteria will be offered an opportunity to participate in this research study. These individuals will be approached to offer participation in this study. Informed consent and HIPAA authorization forms will be obtained. Candidates will be recruited either in the physicians offices or pre-operatively. If criteria is met for recruitment, and potential candidate is interested in participating after a full explanation of the research, informed consent will be obtained. Within two weeks of preoperative admission, the participant will be given the Demographic Data Sheet (DDS), The Numerical Rating Scale (NRS) and General Comfort Questionnaire (GCQ) to complete. Within ten minutes of PACU admission and at PACU discharge, the NRS will be assessed as standard of care. Final assessment will be completed within sixty minutes of arrival to medical/surgical room, the NRS and GCQ will be repeated. Medical Record Evaluation will provide medications received intraoperatively and in PACU. This will place participant in Group A or B.

7.0 MEASUREMENT OF EFFECT

Demographic Data Form:
Fourteen items are on the Demographic Data Sheet (DDS). A one time completion of DDS will be evaluated with an Estimated Time for DDS completion < 5 minutes. This questionnaire will collect data documenting age, marital status, ethnicity, education level, socioeconomic status, race, history of chronic pain, daily pain medication list, cigarette smoking, exercise, hair color & how participant deals with pain and what alternate emotional/spiritual may have been used in the past to improve comfort and reduce pain.

Numerical Rating Scale (0-10 Pain Scale):
Numeric Pain Rating Scale (NRS) will ask the participant to rate intensity of their pain on a 0-10 scale. This self report of pain describes pain in a numeric form on a graduated scale with 0 = No Pain and 10 = Severe pain or worst pain imaginable (NIH, 2003). Use of the Numerical Rating Scale (NRS) has been established as reliable and valid (Williamson & Hoggart, 2005). The NRS is frequently used in the postoperative period to evaluate pain. Numerical Rating Scale will be evaluated four times (pre-op, post-op upon PACU arrival and discharge, and upon arrival to medical/surgical unit). These measures are done by registered nurses. Education will be provided to all nurses regarding the Numerical Rating Scale. The following script will be used to rate pain: "On a scale of 0-10, 0 = No pain, 10 = Worst pain, please rate your pain. There is no right or wrong answer". Estimated time to completion NRS < 1 minute.

Appendix K (continued)

General Comfort Questionnaire (GCQ):
A 28 item 6 response multiple choice likert scale instrument rating from strongly agree to strongly disagree (Kolcaba, 1992). Several modifications of this instrument are available with high reliability. Initial results for the original form of the Principal Components Analysis (PCA) showed all items measuring a single construct with a Cronbach's alpha = 0.88 (Kolcaba, 1992). Thirteen factors were extracted with eigenvalue > 1 (Kolcaba, 1992). Revised reliabilities increased Cronbach's alpha = 0.90 (Kolcaba, 1992). This instrument showed statistically significant sensitivity in the expected directions between several groups (Kolcaba, 1992). This questionnaire will be completed one time pre-op and one time post-operatively (medical-surgical unit). This questionnaire takes about 10-15 minutes to complete.

Chart Review for Grouping & Data Analysis: Medications used in the OR and PACU will be recorded as well as participant age, height, weight, length of PACU stay and NRS score.

8.0 DATA MANAGEMENT
All hard copy information will be kept in a locked & secure drawer in the Anesthesia CRNA Office with limited access to Primary PI. All electronic data will be stored on a secured username & encrypted password computer and flash (USB drive) which will be locked in the secured information drawer when not in use by the PI. Microsoft Office Exel & Microsoft Office Word with be created for information gathering and database use.

9.0 STATISTICAL CONSIDERATIONS
9.0.1 Specific Aim 1 is to explore the effect of 2 groups of pharmaceutical regimens on pain and comfort in the laparoscopic robotic prostatectomy patient. The null hypothesis: Pain and comfort will not vary among the two pharmaceutical regimens.

Group A: Opioids
Group B: Opioids + α 2 agonist

Data will be summarized as means and standard deviation for continuous variables and frequencies for categorical and discrete variables. Baseline demographics and preoperative variables will be compared by treatment. Because a randomization for this study is not feasible, this will allow us to check for unbalance between treatment arms. If any unbalance is found, we will use model adjustment to account this. For the primary outcome, pain and comfort will be measured before surgery and at 3 post surgery time points. To test the treatment effect on pain scale score and comfort score, we will use a hierarchical linear modeling (HLM) where level 1 is the individual observation repeated over time and level 2 is the individual within which the observations are nested. Compare to a more traditional repeated measure ANOVA, this maximum likelihood based method will allow us to use all available data the individual provides, even if some of it is missing. We will also adjust for any unbalanced factors that were identified in the preliminary analysis by including them as covariates. The model will also include time of the assessment, treatment arm and the interaction between treatment and time. Because this is a pilot study, we will not adjust for multiple comparisons.

Appendix K (continued)

9.0.2
Specific Aim 2: The specific aim 2 is to explore the relationship between pain and comfort in post-operative RALP patient. The null hypothesis: Decreased pain will not be associated with increased comfort.

We will use simple bivariate correlations. The correlations will be computed at each time point and tested against the correlation of zero.

9.0.3
Determination of Sample Size
Poser was first assessed for the repeated-measures ANOVAs. Simulations have been shown that HLM and repeated-measures ANOVAs have similar power pattern when same data were used (FANG, 2006). We expect our method will be three groups in the study: because all partially observed data re included. There will be two groups in the study:

Group A: Opioids
Group B: Opioids + α 2 agonist

There will be two dependent variables for the ANOVAs (pain scale score, comfort score); each will be evaluated on the interval scale of measurement. Therefore, the study will employ two, repeated-measures ANOVAs, one ANOVA for each of the two dependent variables.

A priori power was estimated for the univariate repeated-measures ANOVAs. The analyses assumed that the sphericity requirement was met (Stevens, 2002; Tabachnick & Fidell, 2007). The proposed analysis will use a two-tailed alpha level set to .05. Overall power was set to .80, meaning the study will have an 80% probability of finding a significant difference if such a difference exists in the population. Equal sample sizes were assumed. The power analysis concentrated on the multivariate group-by-time interaction because4 it usually is the least powerful element in a repeated measures ANOVA (Field, 2009; Wickens & Keppel, 2004). A medium effect size was anticipated (Cohen's {1988} $f = .25$). Results showed an overall sample size of 38 would be required (19 subjects per group), assuming the correlation between the observation from the same subject is at least 0.2. This sample size was selected as the smallest sample that would be important to detect. Recruitment will continue until both groups A & B of 23 per group are filled. This will assume 15% attrition.

The study will also calculate the bivariate association between pain and comfort scores for robotic laparoscopic prostatectomy patients. Therefore, a second power analysis was completed. Power for the bivariate analysis was set to .80. A large effect size was postulated (i.e., Cohen's {1988} $r = .50$. Results showed that an N of 26 would be required.

Given the discrepancy between the two power analyses, the more conservative sample size will be employed. In other words, the sample will employ 46 participants. This sample size will be sufficient for both the repeated-measures ANOVAs and the bivariate-correlation analyses.

Appendix K (continued)

10.0 HUMAN SUBJECTS

Protection of Human Subjects

The study introduces little risk for subjects. Vulnerable populations such as age have been restricted in this study setting parameters at > 18 years of age since < 18 years of age are considered a vulnerable population. Informed consent will clearly inform individuals of the studies nature. Intent to ensure confidentiality will be clearly indicated within the consent. Potential candidates will review the consent with a written description of the purpose, protocol, risk/benefit of research participation. Participants will be allotted time for discussion, and provided the opportunity to ask questions prior to signing the consent. Upon candidates ability to state purpose and expectations of study, written consent will be obtained. The Principal Investigator (PI) or Sub-Investigator will obtain written informed consent from candidates who meet inclusion criteria. Informed consent will include discussion of a voluntary basis inclusion with ability to withdrawal at any time. Informed consent will be given to the participant, and one kept with the Principal Investigator.

Participant pool will be recruited either in the physicians offices or pre-operatively. In a confidential setting, individuals will be asked if they are interested in participating in the study, if so, consent will be obtained. At this time, an identification number will be assigned to ensure confidentiality requesting all participants to place this number on any paperwork. This information will be stored in a locked file cabinet by the PIs. Only the PIs will have access to this information. Data will be transcribed to a secure computer and accessed only by the PIs, further password protected. Analysis of data will occur in month 4 with manuscript preparation in month 5. After project completion, all information will be kept in a locked secure location by the Primary PI for seven years, after which time the data will be shredded and electronic data will be deleted.

Inclusion of Women as Subjects
The RALP procedure is performed only on men, which excludes women from this population of interest.

Inclusion of Children as Subjects
No children will be recruited for this study, as children are not included in the population of interest.

Inclusion of Minority as Subjects
Statistically, prostate cancer has a higher prevalence in African American men than Caucasian men. There are no exclusions for minorities in subject recruitment. All ethnicities that meet the study inclusion criteria are eligible.

Appendix K (continued)

Data and Safety Monitoring Plan

This study will not implement a Phase I, II, or III clinical trial, so a formal data and safety monitoring plan will not be proposed.

Compensation to Subjects

There will be no compensation provided to the study participants.

Vertebrate Animals

This study is using human subjects only.

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Appendix L

Curriculum Vitae

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Experience

1989-1997	Episcopal Hospital (Staff RN Med. Surg., ICU & PACU)
1993-1999	Home Health Corporation of America (Home infusion RN)
1997-1998	Thomas Jefferson University (Staff RN Pain service/PACU)
2000-2002	MCP/Hahnemann University (CRNA MCP)
2004-2007	Thomas Jefferson University (CRNA pool)
2008	Presbyterian University (CRNA full time June-September)
2002-present	Fox Chase Cancer Center (CRNA full time)

Education

2015	Drexel University, Phila., PA, Doctoral Nursing Program - DrNP
2008	Dublin, Ireland, International Education Study Abroad (2 week internship in April)
1998-2000	Drexel University, Phila., PA, Nurse Anesthesia Program - MSN
1993-1995	Thomas Jefferson University, Phila., PA, Nursing Program - BSN
1987-1989	Episcopal Hospital School of Nursing, Phila., PA – Nursing Program - Diploma
1985-1987	Community College of Philadelphia, Philadelphia, PA

Additional Professional/Personal/ Experience

2005-2013	Clinical Coordinator for Student Registered Nurse Anesthesia Program at Fox Chase Cancer Center for University of PA from
2010-2013	Clinical Coordinator for Student Registered Nurse Anesthesia Program at Fox Chase Cancer Center for Thomas Jefferson University
2009 - 2012	Editor of International Student Journal of Nurse Anesthesia
2009-2013	Educator Nurse Anesthesia Program University of PA N793 On-Line Blackboard Discussion Board 6 week summer course Simulation Lab: University of PA worked with SRNAs in simulating Anesthesia scenario's
2010-present	Board Member Summer Sands Condominiums in Wildwood Crest, NJ