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Evaluation of the Temporal Artery Thermometry to Assess Accuracy when Compared with Body Core Temperature in the Operative Environment

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EVALUATION OF THE TEMPORAL ARTERY THERMOMETRY TO ASSESS ACCURACY WHEN COMPARED WITH BODY CORE TEMPERATURE IN THE OPERATIVE ENVIRONMENT

INTERNSHIP PRACTICUM REPORT

Presented to the Graduate Council of the Graduate School of Biomedical Sciences
University of North Texas Health Science Center at Fort Worth

In Partial Fulfillment of the Requirements

For the Degree of

MASTERS OF SCIENCE

By

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Fort Worth, Texas

May 2009
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CHAPTER I

INTRODUCTION

The Research and Education Institute (TREI) for Texas Health Resources (THR) is an independent and non-profit organization which is actively involved in conducting and coordinating clinical research studies across their 13 affiliated hospitals. As a clinical research management graduate student at the University of North Texas Health Science Center (UNTHSC), I was given with the privilege to intern at TREI for 6 months, which provided an opportunity to obtain hands-on experiences in the clinical research field. The mission statement of TREI lies in conducting medical research, offering educational programs, and undertaking development projects that contributes to the prevention, diagnosis and treatment of disease (19). Currently, there are 10 different ongoing studies; an Alzheimer drug study, a Congestive Heart Failure Telemanagement program, a lower back pain treatment study, the XIENCE stent post approval data collection study, a Chronic Obstructive Pulmonary Disease (COPD) drug study, 3 Gastric Esophageal Reflux Disease studies, a Nurse Walking Study, an Sequential Compression Device (SCD) sleeve Comparison study, along with my assigned Temporal Temperature Comparison project. During my internship at TREI, I was first under the mentorship of Laurie Comeau, B.S; manager of clinical research. After her departure from TREI, Teresa Turbeville, B.S. assumed the role as my mentor. She is a director of research at TREI.
Delegation of responsibilities to design, oversee, and conduct the temperature study was given to me. I was challenged with designing and conducting a study which assesses the accuracy of the temporal scanning thermometer and comparing its measurement of temperature to the measurement of core body temperature using an esophageal temperature probe. This study was conducted in the operating rooms of Harris Methodist Southwest hospital (HMSW) and Harris Methodist HEB hospital (HEB), which are affiliated hospitals of THR. The temperature study was conducted in an attempt to prove the accuracy of temporal artery thermometry when compared to core body temperature, so that it can be used in situations where measuring core body temperature is critical but a non-invasive method of measuring temperature is preferred. Human subjects of male and female gender, between the ages of 18 and 65 years, and all ethnicities were recruited for the study. The principal investigator on the temperature study, Leslie Rodriguez, MPH, BSN, RN, CPAN, seeks to investigate and evaluate the accuracy of temporal artery thermometry and determine if the non-invasive temporal artery thermometry can replace the esophageal temperature probe to measure the core body temperature by medical staff.

Developing the protocol for this study was a valuable and challenging experience because numerous revisions to the protocol were required. During the conduct of this study, I learned how to demonstrate good clinical practice skills while completing the internship practicum. Helping with other currently ongoing studies and the closed studies at TREI definitely enhanced my knowledge in clinical research. Finally, conduct of the study conducted during my Internship Practicum will help determine and further evaluate whether temporal artery thermometry is equivalent to the measurements of core body temperature. The clinical significance of this study is that its findings may be utilized to help medical staff to confidently measure the temperature with temporal artery thermometry in the future.
CHAPTER II

INTERNERSHIP SUBJECT

BACKGROUND AND LITERATURE REVIEW

Thermoregulation is the ability of an organism to keep its body temperature within certain boundaries, even when the surrounding temperature is very different. The skin assists in homeostasis in humans keeping different aspects of the body constant for example, temperature (22). Vasodilation and sweating are the primary modes by which humans attempt to lose excess body heat. In hot conditions, peripheral sensory thermo-receptors underneath skin senses high temperature in the surrounding environment and send a signal to a part of brain which integrates the input information. Then, the brain sends the stimulus to sweat glands under the skin to secrete sweat. Sweat is a fluid containing mostly water along with some dissolved ions. Sweat travels up the sweat duct and through the sweat pore and onto the surface of the skin. This causes heat loss by evaporation. Also, the hairs on the skin lie flat, preventing heat from being trapped by the layer of still air between the hairs. This is caused by tiny muscles under the surface of the skin called arrector pili muscles relaxing so that their attached hair follicles are not erect (22). These flat hairs increase the flow of air next to the skin increasing heat loss by convection. Sweating is the only physiological way for humans to lose heat, when environmental temperature is greater than core body temperature. Additionally, vasodilatation of the arterioles also occurs. This is the process whereby relaxation of smooth muscle in arteriole
walls allows increased blood flow to occur through the capillary bed of skin increasing heat loss by radiation and conduction (22).

However, in cold conditions, sweat production is inhibited. The arrector pili muscles contract, lifting the hair follicle upright. This makes our hairs “stand on end” which acts as an insulating layer, trapping heat. This is what also causes “goose bumps”, and since humans do not have much hair the contracted muscles can be easily seen (22). Arterioles carrying blood to superficial capillaries under the surface of the skin can constrict, thereby rerouting blood away from the skin and towards the warmer core of the body. This prevents blood from losing heat to the surroundings and also prevents the core temperature dropping further (22). This process is called vasoconstriction. It is impossible to prevent all heat loss from the blood, only to reduce it. In extremely cold conditions excessive vasoconstriction leads to numbness and pale skin. Frostbite only occurs when water within the cells begins to freeze; this destroys the cell causing damage. Muscles can also receive messages from the thermo-regulatory center of the brain called the hypothalamus that causes shivering (22). This increases heat production as respiration is an exothermic reaction in muscle cells. Shivering is a more effective mechanism than exercise at producing heat because the animal remains still.

Regulation of internal core body temperature within a narrow range is vital for the well-being of humans (10). Body temperature measurement is a routine part of daily standard of care for those patients entering a hospital for surgery or other purposes. Body temperature is measured using a variety of methods including oral, rectal, temporal, tympanic, esophageal, urinary bladder, pulmonary artery, etc. A disadvantage of all measuring methods mentioned, however, is that they do not reflect the actual core body temperature that prevails at the level of the hypothalamus of the brain-the ‘thermostat’ of the human body. The internal organs in the
human body experience fluctuations in temperature and the only true core temperature is that existing in the hypothalamus, because that is the location of the temperature control center of the human body (9). However, of these methods, one of the most accurate tools to measure core body temperature is accomplished with a pulmonary artery catheter. The pulmonary artery bathes the catheter with blood from the body core and its surroundings (7). A disadvantage, however, is that it is impossible to measure pulmonary artery temperatures in daily situations, so other methods than those applied in an intensive care situation have to be used for determining the core temperature. The question now is how to measure the core temperature as accurately as possible in the non-clinical environment (9).

Measuring a patient’s body temperature is a routine part of the physical exam to determine whether a person has spiked a temperature, indicating illness. Body temperature can be easily assessed in the home or clinical setting. Accurate temperature measurement is critical to the assessment and management of temperature fluctuation in the acutely ill adult as well as children. Elevation of body temperature may be indicative of infection (7) or adaptation to the ambient temperature. There are several methods available for measuring body temperature, however, the most accurate method to measure the temperature has not yet been established. Sometimes, errors by the assessor or errors from the device itself can produce detrimental results; thus, measuring temperature is a practice that should not be overlooked and should be done cautiously.

Patients may experience body temperature fluctuations during their stay in the hospital. The ideal temperature measuring instrument should offer a measurement close in proximity with core body temperature. It should be simple to use, fast and inexpensive (11). Temporal artery thermometry is better tolerated than rectal thermometry by both pediatric and adult patients as it
eliminates the embarrassment factor, is painless, and much faster. It is also safer because no
body orifices are entered, thereby eliminating the risk of perforation (14). This practicum study
was designed to find whether temporal (scanning) temperature monitoring is an accurate and
useful method for body temperature measurement. For this purpose, measurement of body
temperature with a temporal artery thermometer was compared with esophageal/core
temperatures.

Accurate measurements of body temperature by non-invasive thermometers have yet to
be established (7, 11). The most accurate method of temperature measurement is performed
using a pulmonary artery catheter and esophageal and urinary bladder core temperature probes;
however, to use one of these methods, one must be in a critical care setting. There are many
patients that will be cared for by professionals outside the critical care setting and accurate
measurement of body temperature will provide additional information to the providers of the
patient’s routine healthcare.

Many studies have concluded that different types of thermometers, including the
temporal artery thermometer, are accurate in children (6, 14, 15, 18); rectal thermometers have
been reported to be most accurate for children younger than three months of age (2). However, it
has been reported that the rectal temperature response to changes in core body temperature is not
as fast as the temporal artery temperature (5). This is possibly due to the fact that the rectum is
better insulated and is thought to be less influenced by external factors (4). In contrast, other
studies concluded that only in stable conditions would the temporal artery thermometer provide
reliable temperatures (8, 17, 12).

Despite of ongoing controversy, there are no doubts that the temporal artery thermometer
is an easy-to-use, quick and non-invasive device. This method involves the use of an infrared
scanner that detects the highest temperature of forehead skin, presumably from the temporal artery (10). The temporal artery is close to the skin surface, easy to access, and use of the temporal scanner is less prone to operator error (3). The temporal artery is a branch of the external carotid artery that arises from the common carotid artery. The common carotid artery, in turn, is connected to the heart via the brachiocephalic trunk and aorta on the right side of body, or directly off the aorta on the left side. Thus, it offers a constant source of blood flow (Figure 1) to the temporal region. Furthermore, the temporal artery is the only artery positioned close enough to the skin surface (within 2 millimeters) to provide the access needed to take an accurate measurement (11).

Figure 1: Anatomy of Temporal Artery (21). Reprinted with permission from Exergen Corporation (Appendix A).
The temporal scanning thermometer measures the naturally emitted infrared heat from the arterial blood supply at approximately 1000 “frames” per second, locking in the highest temperature it senses (11,21). From this value, the device estimates core temperature using proprietary algorithms that incorporates compensation for the ambient temperature and “standard” temperature gradients from the skin to the body’s core (10). Peripheral vasoconstriction may influence the accuracy of the measurements with the temporal scanner. However, a study conducted by Myny, Waele, Defloor, Blot and Colardyn in 2005 (11) reported that the use of vasoactive medication was not an influencing factor on the Temporal Artery Thermometer values. This finding is important in intensive care units because many patients in this setting received vasopressor therapy (11).

According to Hooper and Andrews (7), measurements using the temporal artery thermometer compares favorably to the tympanic and rectal temperature measurements. The temporal scanner has a relatively good reliability with an acceptable accuracy and variability in patients with normothermia (11). Reliability refers to the ability of an instrument to provide consistent measurement of a variable (3). However, little is known about the temporal artery temperature measurements when compared to the core esophageal temperature measurements in the adult population who are undergoing surgical procedures. Induction of either general or regional anesthesia impairs thermoregulation, allowing a redistribution of heat from the central compartment of the body (consisting primarily of the major internal organs) to the periphery. In addition, heat is lost to the cold operating room environment over time, furthering the heat deficit that will ultimately be repaid post-operatively (20). The temperature of the external environment is known to affect body temperature. The heat regulating center, the hypothalamus maintains core body temperature by controlling the rate of heat loss through the skin, mainly by adjusting
the degree of vasodilation/vasoconstriction of the blood vessels. However, the hypothalamus can only achieve this within certain limits. If ambient temperature falls too low, the body is unable to retain heat and may become hypothermic (core temperature < 36º C) (4). Very young, very old, and very sick patients are more likely to become hypothermic during anesthesia and surgery regardless of the surgical procedure. Additionally, certain procedures exacerbate peri-operative hypothermia by their duration or field exposure alone (20). Apparently, patients who undergo anesthesia and surgery do not always have stable core temperatures during the operations.

A goal of this practicum was to collect additional evidence to demonstrate the accuracy of the temporal artery thermometer for body temperature measurement even during unstable conditions. Currently, at Harris Methodist Southwest hospital and Harris Methodist HEB hospital, the operating room uses the Vitaltemp™ esophageal temperature probe manufactured by Vital Signs Incorporated (Totowa, NJ) to measure core body temperature, as well as the Exergen temporal scanning monitor thermometer (Model TAT -5000) manufactured by Exergen Corporation (Watertown, MA) to measure external body temperature. The temporal thermometer is shown in Figure 2. Studies conducted for this practicum compared the temporal temperature to esophageal core temperature using the Exergen temporal scanner to assess the reliability and accuracy of temporal thermometry during the surgical procedures.

Figure 2. Exergen Temporal Artery Thermometer measuring a child’s temperature (21). Reprinted with permission from Exergen Corporation (Appendix A).
SPECIFIC AIMS

The hypothesis for this study is that measurement of body temperature using the temporal artery thermometer temperature is consistent to core body temperature measurement using an esophageal probe within 1 temperature grade in Celsius. The primary objective of this study is to evaluate the temporal artery thermometry and its accuracy and reliability to measure body core temperature. The goal is to find out how accurately temporal artery thermometry measures the core temperature in a population which has had anesthesia induced surgeries.

An infrared temporal artery thermometer, which is a hand held temperature measuring device called the Exergen Temporal Scanner, will be used to measure the temporal temperatures. A Vitaltemp esophageal temperature probe will be used to measure the core temperatures in patients in operation rooms.

SIGNIFICANCE

There is very little evidence or published and research validating the accuracy of temporal temperature measurements when compared to core body temperature measurements. This Internship Practicum Report will help determine and further evaluate whether temporal artery thermometry is equivalent to the measurements of core temperature. Moreover, this report is significant in that its findings maybe be utilized to help medical staff to confidently measure body temperature using temporal artery thermometry. Inaccurate temperature readings can ultimately lead to incorrect diagnoses, delay of appropriate treatment, and subsequent permanent injury or even death (10). The accuracy of temporal artery scanners for the measurement of body temperature is controversial. Therefore, the outcome of this study will help to validate that
temporal artery scanner is as accurate as other methods such as pulmonary or esophageal temperatures probes to measure core body temperatures.

MATERIALS AND METHODS

Before data collection began, it was necessary to hold an in-service among the hospital staff. Measuring the core temperature once inside the operation room is done as a standard of care for patients by anesthesia providers. However, patients must sign the designated informed consent forms in order to allow study staff to measure their temporal temperature using the Exergen Temporal Scanner every 15 minutes during the operations. Investigators were trained on the appropriate use of the device by strictly following the instructions accompanying the device. The study staff was instructed to position the probe in the middle of the forehead, depress, and hold the “on” button, move the probe laterally to the hairline, stop, and release the “on” button unless there was perspiration on the forehead. If the patient was diaphoretic (perspiring profusely; refer to Figure 3), the study staff was instructed to keep the “on” button depressed behind the earlobe before releasing the “on” button. Touching behind the earlobe (refer to Figure 4) compensates for any cooling that might result from perspiration on the forehead and is only necessary if the patient is diaphoretic (13).
The image from Figure 3 illustrates how the effect of evaporative cooling on the forehead of a sweaty patient would erroneously lower the temperature. The one critical requirement for measuring arterial temperature is vasodilation. The temporal artery has no appreciable vasomotor activity, and as such, maintains a nearly constant rate of perfusion (11). Note the redness of the neck in the image above that is indicative of vasodilation. Sweat usually first appears on the forehead area, and lastly on the neck area, thus making the forehead an excellent area on which to use the temporal artery thermometer. By measuring both the area over the temporal artery, and the area behind the ear on the neck, the temporal artery thermometer will capture the highest of 3,000 uptakes, selecting the highest pinpoint of heat it detects. An excessively wet forehead, as found in diaphoretic patients, prevents the device from scanning the highest temperature on the forehead and the neck will override by providing the site of vasodilation with higher temperature than the one from the forehead. However, if the forehead is dry, as in normal patients without diaphoresis, the measurement on the neck is a “throwaway”, meaning that it was unnecessary due to lack of vasodilation in the neck but sufficient vasodilation of temporal artery in the forehead. However, scanning both the forehead and the
neck eliminates discretion and allows for uniformity in the measurement as everyone is standardized on the technique. If the patient is completely soaking wet, you cannot wipe the sweat away quickly enough to have any effect on the measurement. At this point, the patient's temperature drops off rapidly and fever is not an issue. The best procedure in this instance would be to return in about 10 minutes and take a temporal artery temperature when the patient is relatively dry (21).

Figure 4. Measuring behind the ear lobe; a touch of insurance (21). Reprinted with permission from Exergen Corporation (Appendix A).

Figure 5. Normothermia in an adult; High resolution infrared image (21). Reprinted with permission from Exergen Corporation (Appendix A).
It is not uncommon to observe health care providers when using the temporal probe scan down the side of the face following the curve of the eyebrow. The thermal images shown in Figure 5 demonstrates that a scan down the side of the face is apt to miss the temporal artery altogether as the temporal artery is situated fairly deep in that area and varies from individual to individual. Scanning down the side of the face also results in non-reproducibility of the readings. Whereas, scanning straight across the temporal artery (refer to Figure 6) produces reproducible results if approximately a 30 second lapse occurs between scans to allow the skin to recover from the cooler probe of the thermometer (21).

Figure 6. Correct way of using the Scanner; Scan across the forehead (21). Reprinted with permission from Exergen Corporation (Appendix A).

Figure 7. Twins: Afebrile (left) and Febrile (right) (21). Reprinted with permission from Exergen Corporation (Appendix A).
Once the Institutional Review Boards (IRB) of Texas Health Resources and the University of North Texas Health Science Center in Fort Worth approved the study, data collections began at the operating room at Harris Methodist Southwest (HMSW) Hospital in Fort Worth. Harris Methodist HEB (HEB) Hospital in Euless/Bedford began the study about a month later after a study coordinator for the project was appointed. After review of the inclusion and exclusion criteria with possible candidates, the subjects were required to sign informed consent forms. Temperatures inside the operations rooms were recorded, and correspondingly filed in the study charts.

**Recruitment of Subjects:** Subjects were recruited from the pre-operative area prior to admission to the operating room or from the outpatient surgery pre-assessment center a few days before their surgical procedures. Each subject was approached in a private setting for the informed consent process. Each subject was pre-screened by review of inclusion and exclusion criteria. Each subject could ask as many questions as they desired. Only those subjects that understood and agreed to the study were consented. All subjects were given a signed copy of the consent form. The original was placed in the study folder and a copy was placed on the patient’s hospital chart. Each patient was asked to sign the informed consent form before participation.

Only subjects who were to have the esophageal temperature probe during the operations to measure the core temperature were enrolled in the study. Patients who had certain types of surgery such as facial or neck were excluded from the study in order to avoid study staff getting in the way of surgeons in the sterile fields. If the patients had a Laryngeal Mask Airway (LMA) in their esophagus during the operations due to medical reasons, their temperature was measured using other methods, such as axillaries or nasal. Therefore, patients who had LMAs were
excluded from the study or recorded as screen fails. Patients who required the Bair Hugger® warming system (manufactured by Arizant, Incorporated, Eden Prairie, MN) intra-operatively were included in the study. The Bair Hugger® warmer injects warm air into a disposable plastic/paper quilt-like blanket. The warm air exits slits in the patient side of the blanket, providing a microenvironment of warm air around the subject (16).

Depending on the types of surgery a patient was expected to have and the medical problems of the patient, an anesthesiologist determined whether the patient would be intubated with an esophageal temperature probe as part of “a standard of care”.

**Selection of Subjects**: Subjects were selected based on the following inclusion and exclusion criteria.

**Inclusion Criteria:**

1) Adult subjects that can speak and understand English.

2) Adult subjects that can read and understand the English consent form.

3) Adult subjects admitted to the operating room with an esophageal thermometer at Harris Methodist Southwest (HMSW) or Harris Methodist HEB (HMHEB).

4) Subjects older than 18 years old but less than 65 years old.

5) Subjects without any disease that would interfere with measuring core body temperature through esophageal thermometry.

6) Subjects willing to allow medical staff to perform forehead temperature acquisitions along with esophageal temperature monitoring every 15 minutes, while they are in the operating room.
**Exclusion Criteria:**

1) Adult subjects that cannot speak and understand English.

2) Adult subject that cannot read and understand an English consent form.

3) Subjects that are less than 18 years of age or greater than 65 years old.

4) Adult subjects that are not admitted for surgery at Harris Methodist Southwest (HMSW) or Harris Methodist HEB (HMHEB).

5) Adult subjects who have the warming devices covering the area being measured using a temporal artery thermometer anytime during the procedures.

6) Adult subjects with a skin rash on the forehead or any diseases that would interfere with temperature monitoring by esophageal thermometry.

7) Subjects who were undergoing facial, neck or neurosurgical procedures that would preclude touching the sterile fields.

8) Subjects whose core temperatures will not be monitored using esophageal temperature probes during the procedures, such as patients who have a Laryngeal Mask Airway (LMA). Their temperature will be monitored by nasal or axillaries temperature recordings instead.

9) Subjects unwilling to allow medical staff to obtain forehead temperature readings along with esophageal temperature monitoring every 15 minutes while they are in the operating room.

10) Any subject that the principal investigator considers not appropriate for this study.
**Procedures:** The following procedures related to the conduct of this research project were performed during the conduct of this study:

Upon entering the HMSW or HEB Operating Room:

1. The subject’s core esophageal temperature was measured using an esophageal thermometer probe every 15 minutes while in the O.R and was performed by study coordinators by reading temperatures off a monitor.
2. The subject’s forehead temperature was measured using a hand-held unit, Exergen Temporal Scanner unit every 15 minutes while the subject was in the OR. This reading was also obtained by a study coordinator.
3. The study coordinator recorded these temperatures on a log sheet.
4. After the subject’s temperature readings were recorded, the data was considered completed.

If for any reason temporal temperature could not be assessed from the patients during the procedures, then they were withdrawn from the study. The procedures in this research study were considered to be standard. “Standard Procedures” are performed even if subject did not take part in this study.

This study originally proposed to enroll and collect the data from at least 100 patients at the HMSW hospital and HEB hospital, i.e., 50 subjects at each hospital. The study was conducted in the operating room. The inclusion/exclusion criteria were reviewed with each patient, in a private area within pre-operative services or the out patient surgery center. Those who qualified were approached for this study. All study subjects were explained the study in detail and allowed time to ask questions. Those who voluntarily agreed to participate in this
study signed a consent form and were given a copy. A copy was also placed in their patient chart. The original was kept in the study file. After consent, and upon entrance into the operating room, each study subject had their temporal temperature and their core body temperature recorded every 15 minutes, for the duration of the surgery or up to 2 hours. The data was recorded and later placed on a spreadsheet for future analysis. After temperature measurements were collected during the operations, the study subject completed the requirements for this study.

**Statistical Analyses:** This study used the paired t-test to determine sample size.

Study sample size should be a total of 100 subjects, with 50 patients at each hospital (45 + 5 subject exclusions or 10% for possible exclusions to study). Thus far, a total of 30 subjects from HMSW have been enrolled. The sigma stat 3.1 program was used to determine a study sample size of 45 for one site. The paired t-test examining a relationship was used in conjunction with a desired change of 0.5, a standard deviation of 1.0, a power of 0.9, and an alpha of 0.05. The subjects were matched and interval data was collected. A confidence interval of 95% was proposed. The correlation sample size = 38 of one site will be completed as we plan to enroll 45 patients in this study at each site. Final study analysis will use the correlation coefficient “r” test (within SPSS software) determine the relationship between the two variables (temporal and core body temperature). Also, Bland and Altman analysis will be conducted to determine the level of agreement between the two measurements. Ideally, the mean difference would be zero over the entire range of measurements (1). Possibly, the paired t-test may be used for statistical comparison to see if the means on these two normally distributed interval variables differ from one another. Appropriate data analysis will be performed in order to interpret the data and hopefully, the data will demonstrate that the temporal artery thermometer temperature will
consistently relate to core esophageal temperatures within 1 degree temperature grade in Celsius from the obtained data.

**Potential Risks & Benefits:** Measuring temporal body temperature is non-invasive and therefore does not pose any risks to the study patient. Core body temperature using an esophageal temperature probe is invasive but is done routinely in the hospital setting. Core temperature was collected only if it was part of routine care of each study subject, as determined by the subject’s anesthesiologist. Standard of Care risks for placement of an esophageal temperature probe may include infection or sore throat. Choosing not to participate in this study did not affect the patient’s standard of care while in the hospital.

There were no benefits to the subjects for participating in the study. Subjects were not paid for participation. However, accuracy of temperatures is of vital importance for any ill patient and maintaining body temperature within a narrow range during the operation period and afterwards is very important for the well-being of patients. The most accurate and efficient means of taking a temperature of an ill patient should be established for healthcare providers in order that patients receive the best care for their illness. The least invasive way to measure the core temperature during the operation and afterwards should ease the recovery period of patients. In the future, it will allow healthcare providers to confidently take patient’s body temperature with a forehead monitor, which is quick and easy to use. The information learned from this research study will undoubtedly benefit other patients in the future by helping us learn which method of measuring the temperature is most accurate and easiest to use.
RESULTS AND DISCUSSION

The study started on December 18, 2008 when the first patient was consented for the study at HMSW. The study is expected to end when the number of people required for the study is met at HMSW and HEB. Since the desired enrollment goal has not been met yet, the study remains open and ongoing. The data presented herein are the result of this ongoing study obtained as of February 6, 2009 at HMSW.

![Pie chart of the patients who were screened for the study in percentages](image)

Figure 8: Pie chart of the patients who were screened for the study in percentages

During this period of data collection, there were 41 patients who met the inclusion/exclusion criteria pre-screening for this study out of numerous patients who had their surgical procedures done at HMSW. As shown in Figure 8, a total of 30 (73%) patients were enrolled into the study and completed the entire study. There were 8 (20%) patients who did not qualify to be in the study and 3 (7%) patients who were not interested in participating in the study. Those 8 patients were disqualified to be in the study due to the several reasons: 1) Two patients had upper body Bair Hugger® during their procedures, which was the original protocol deviation before an amendment was made to the protocol. 2) Two patients who had met all the inclusion/
exclusion criteria had to be withdrawn from the study due to the position placed on the table during the procedures. Their foreheads were not accessible to measure the temporal temperatures every 15 minutes during the procedures. 3) There was one patient whose data was collected every 10 minutes instead of 15 minutes during his procedure by one of the Certified Registered Nurse Anesthetist (CRNA), which was a definite protocol deviation. 4) Three (3) patients were disqualified to be in the study because they had a Laryngeal Mask Airway (LMA) placed instead of having endo-tracheal tubes with esophageal temperature probes due to the medical reasons such as having diabetes. The Laryngeal Mask Airway is an alternative airway device used for anesthesia and airway support, and an anesthesiologist determines whether a patient receives it during the procedure after reviewing the patient history and current medical situations. Temperatures were monitored in alternative ways such as nasal or axillaries on these people who received LMAs during their procedures so their core body temperatures were not available.

The experiment was conducted on each patient by measuring temporal temperatures using an Exergen temporal artery thermometer along with esophageal core temperature readings off the anesthesia provider’s monitors every 15 minutes, up to 2 hours, which allowed the collection of at least 3 to 8 measurements per subject depending on the length of the procedure. Some surgical procedures were very short such that only 3 measurements were collected, while other procedures were longer and yielded up to 8 measurements. This gave a total number of 192 samples from the 30 subjects enrolled. Table 1 shows the demographic breakdown of the patient populations. All 25 (83%) patients were females between the ages of 18 and 65 years old. Approximately 33.3% of the patients were between the ages of 41-50 years old. Approximately 77% of patients had upper body Bair Hugger® during the procedure while only
10% had a lower body Bair Hugger®. A majority of the participants were white (73%). No Asian subjects participated in the study.

Table 1: Patient Demographics

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<td>61-70</td>
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<table>
<thead>
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<th>Gender</th>
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<tr>
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<tr>
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<table>
<thead>
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<td>73%</td>
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<tr>
<td>Black</td>
<td>3</td>
<td>10%</td>
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<td>Hispanic</td>
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<td>Asian</td>
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<th>Bair Hugger</th>
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<td>Lower body</td>
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According to the manufacturer of the temporal artery thermometer, the use of Bair Hugger® or other warming blankets will not interfere with the use of the thermometer as long as the warming devices are not covering the area being measured. Therefore, one of the components of Bair Hugger®, which usually covers the face of the patient during the procedure, was left out for each patient to make sure that the forehead was not covered. Similar techniques of measuring temporal temperature were employed among the data collectors to assume consistency throughout the study. Measuring behind the earlobe is a part of the proper technique to measure the temperature using Exergen temporal artery thermometer and was performed on
each subject; especially, for the diaphoretic patients who sweated excessively on the forehead. However, this practice prevented collecting precise temperatures on some patients who had an upper body Bair Hugger® during the procedures because warm air of 42 C° constantly blew through a tube slipped out around the neck region. This increased the ambient temperature behind the earlobe area. As a result, the Exergen thermometer read unexpectedly higher temperatures at times than the actual core body temperature in patients with an upper body Bair Hugger® (Refer to Table 2) Subject numbers, 011, 017, 022, 027 and 028 rendered temporal temperatures around 40 °C at some point during the experimental period. This indicated that body temperature was not normal and the subject was experiencing hyperthermia; however, no single case of hyperthermia was observed based on esophageal core body temperature measurements. Table 2 shows the data collected on all 30 subjects in the study.
Table 2: Sequential temperature measurements measured with Exergen temporal artery (TA) (calibrated already by the manufacturer) and esophageal temperature probe (Eso) every 15 minutes during the procedures on 30 subjects in °C (degrees Celsius)

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</table>
The desired sample size for this study was 50 subjects from each of two investigative sites, meaning 50 patients from HMSW and another 50 patients from HEB. However, the length of time for this practicum was not sufficient to allow for recruitment of all 50 patients at the two sites required for statistical analysis of the data. In this practicum report, the data being analyzed are from the result collected thus far during the time allotted.

There are several reasons of why the study could not be completed during the six months of the internship. First, several amendments to the original protocol were required to incorporate the new findings about the study and also to add one more site and one more study staff to the study. Each amendment had to be approved by two Institutional Review Boards (IRB), which was a time consuming process, and the study could not proceed until the newly revised protocol and the study informed consent were approved by the IRBs. Also, there was a graduate advisory committee member change during the internship practicum because one of the original members relocated and a new member was assigned. Re-designing the protocol was time consuming as well.

Another reason for the delay in beginning the study was the busy schedule of the principal investigator, Leslie Rodriguez. Due to his busy schedule and lack of promptness on queries, the study was often put on halt while waiting on his responses. There were numerous waiting periods for him to finalize the protocol with any revisions when immediate actions were required to submit the amendments in a timely manner. This demonstrates a major factor in the progress of many clinical trials: overworked and overextended physician scientists who have many demands on their time.

Recruitments to enroll the patients into the study took longer than anticipated. There were only a limited number of candidate patients who met all the inclusion/exclusion criteria for
the study. Many patients who are over the ages of 65 years were having surgical procedures and the reason to exclude the patients over 65 years old was due their impaired thermoregulation compared to the patients between the age of 18 and 65 years.

Another reason for the study taking longer than anticipated was that surgical procedures performed on patients while under general anesthesia and with endo-tracheal tubes along with esophageal temperature probes were very rare. Only patients whose foreheads were accessible for measuring temporal temperatures were included in the study. Thus, the position of the patients on the table was another factor that determined their eligibility. Due to many barriers in finding appropriate cases to obtain the data for the study, the study data collection was not completed in an expedient manner.

Lastly, limited resources and personnel to conduct the study was another factor that deterred from completion of the study. Recruiting, consenting, and enrolling subjects and conducting study procedures was the responsibility of the intern: Due to time constraints on one person conducting these tasks, the desired goal to have 50 subjects enrolled in the study at HMSW was not met in the time-frame proposed. There were patients who probably met the criteria for this study but were not included because of time conflicts. Finally, there was only one Exergen temporal artery thermometer initially provided for the study. Until more thermometers were requested and obtained, several cases out of necessity had to be excluded.

Therefore, the study was not completed totally due to the reasons discussed above. The study remains open until the desired number of subjects needed for the study will be met at both sites of HMSW and HEB. The proposed statistical analysis could not be performed due to insufficient sample size. Statistical analyses on the 30 subjects studied to date are presented here. Table 3 shows the descriptive statistics of both temperature measurements. Over all, the mean of
temporal temperature was higher than the mean of esophageal core body temperature by 1.34 °C, which is more than the temperature difference proposed, difference degree of 1°C by the hypothesis. Temporal temperatures ranged from 35.90°C to 42.70 °C, while esophageal core body temperatures ranged from 34.40°C to 37.10°C. Also, temporal temperatures measurements were more variable than the esophageal core body temperatures. The paired T-test comparing temporal temperatures to esophageal temperatures also shows that 95 % of the difference between temporal and esophageal temperatures lies between 1.18°C and 1.50°C, respectively, which is more than 1°C difference. Thus, the rest of the 5% will lie outside of the 95% confidence interval, and the p-value for 2 sides excluding 95% CI is 0.000, which is unlikely to happen. Since the p-value is less than 0.05 (alpha), the T-test shows that it is unlikely that the difference between temporal and esophageal temperatures will be less than 1°C. Therefore, the proposed hypothesis in this practicum report cannot be accepted with currently available data.

Additionally, the correlation coefficient of 0.236 (Table 5) demonstrates that there is no significant correlation between temporal temperature and esophageal temperature, lacking the close relationship between the two devices. The scatter plot shown in Figure 9 supports the conclusion that there is no overall relationship between temporal and esophageal core body temperatures.

Table 3: Table showing the mean, minimum, maximum and standard deviation calculations for the temporal and esophageal core body temperatures for all patients

<table>
<thead>
<tr>
<th>Descriptive Statistics</th>
</tr>
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<tbody>
<tr>
<td>Temporal</td>
</tr>
<tr>
<td>Temporal</td>
</tr>
<tr>
<td>Esophageal</td>
</tr>
<tr>
<td>Valid N (listwise)</td>
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</tbody>
</table>
Abbreviations:
Temporal: Temperature measured using temporal artery thermometer
Esophageal: Core body temperature measured using esophageal temperature probe
N: Total number of sample measurements computed for statistical analyses
Minimum: the lowest temperature collected during the experiment
Maximum: the highest temperature collected during the experiment
Mean: The average of the measurements
Std. Deviation: standard deviation - a simple measure of the variability or dispersion of a data set.

Table 4: Paired T-test analysis comparing the temporal temperatures and esophageal core body temperatures in 30 subjects

<table>
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<th>N</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
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Abbreviations:
Temporal: Temperature measured using temporal artery thermometer
Esophageal: Core body temperature measured using esophageal temperature probe
N: Total number of sample measurements computed for statistical analyses
Mean: The average of the measurements
Std. Deviation: standard deviation - a simple measure of the variability or dispersion of a data set.
Std. Error Mean: The standard error of the mean - the standard deviation of the sample mean estimate of a population mean.

Paired Samples Test

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<th>Sig. (2-tailed)</th>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.34</td>
<td>1.13</td>
<td>.08</td>
<td>1.18</td>
<td>1.50</td>
</tr>
</tbody>
</table>

Abbreviations:
Temporal: Temperature measured using temporal artery thermometer
Esophageal: Core body temperature measured using esophageal temperature probe
N: Total number of sample measurements computed for statistical analyses
Mean: The average of the measurements
Std. Deviation: standard deviation- a simple measure of the variability or dispersion of a data set.
Std. Error Mean: The standard error of the mean- the standard deviation of the sample mean estimate of a population mean.
Confidence interval: an interval estimate of a population parameter
Upper: upper end of 95% confidence interval
Lower: lower end of 95% confidence interval

Table 5: Table showing the relationship between temporal temperatures and esophageal core body temperatures

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Correlation</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pair 1</td>
<td>192</td>
<td>.236</td>
<td>.001</td>
</tr>
</tbody>
</table>

Abbreviations:
Temporal: Temperature measured using temporal artery thermometer
Esophageal: Core body temperature measured using esophageal temperature probe
N: Total number of sample measurements computed for statistical analyses
Correlation: indicates the strength and direction of a linear relationship between two random variables
Sig: test of significance giving a p-value for correlation analyses
Figure 9: Graphic representation of the relationship between temporal temperatures and esophageal temperatures both measured in Celsius

The Bland and Altman graphical analysis is shown in Figure 10. All the data were pooled and demonstrated the poor agreement between the two devices, with mean temperature difference of 1.34°C, which is far from the idealistic zero difference. There are only 3 measurements out 192 samples with zero difference (1.56%), which is statistically insignificant. The horizontal x axis is the average of the two measurements while the vertical y axis is the bias that is the difference of the two measurements. The 95% limit of agreement is (-0.87, 3.55), with 1.13 standard deviation on this study. The defined clinically acceptable bias is ±0.5°C, as this range is within the range of normal circadian body temperature variations and is also consistent with the bias found when comparing different standard core temperature measurement sites (8). The limits of agreement between temporal artery thermometry and esophageal core temperature probe were more than 4 times this clinically acceptable range. Therefore, the Bland and Altman
analysis demonstrates that these devices cannot be used interchangeably and, also, the manufacturer’s claim that the temporal artery temperature can be considered as a core temperature needs to be verified with more evidence and further research.

One of interesting findings of this pilot study is that the difference between temporal temperature and esophageal core body temperature increased over the time during the surgical procedures. The mean difference of first temperature measurements among the 30 subjects was 1.25°C with 0.71 standard deviation, while the last temperatures measurements on the 11 subjects yielded 1.85°C mean difference with 1.33 standard deviation. Throughout the operations, esophageal core body temperature remained stable on all cases while temporal temperatures fluctuation was observed very often. As the duration of the surgical procedure gets longer, the temporal artery thermometer becomes more inaccurate. Possibly, the inaccuracy can be attributable to the prolonged use of Bair Hugger®.
Figure 10: Graphic representation of Bland and Altman analysis of temporal and esophageal temperatures. Upper and lower horizontal lines are the upper and lower limits of agreement, respectively (the limits within which 95% of the differences for the two sets of measurements are expected to lie; the closer these limits are to zero, the better the agreement between the two devices). The solid middle line is the mean difference (systemic bias) between the two devices. The x-axes are the average of the temporal and esophageal derived temperatures.
Table 6: Table showing the descriptive statistics such as mean, maximum, minimum and standard deviation of the difference between temporal and esophageal temperatures over the time measurements were measured every 15 minutes in Celsius (°C)

<table>
<thead>
<tr>
<th></th>
<th>Delta 1</th>
<th>Delta 2</th>
<th>Delta 3</th>
<th>Delta 4</th>
<th>Delta 5</th>
<th>Delta 6</th>
<th>Delta 7</th>
<th>Delta 8</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>30</td>
<td>30</td>
<td>30</td>
<td>27</td>
<td>26</td>
<td>22</td>
<td>16</td>
<td>11</td>
</tr>
<tr>
<td>Mean</td>
<td>0.80</td>
<td>1.25</td>
<td>1.27</td>
<td>1.55</td>
<td>1.49</td>
<td>1.49</td>
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<tr>
<td>Max</td>
<td>2.30</td>
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<td>3.70</td>
<td>5.00</td>
<td>6.60</td>
<td>4.40</td>
<td>3.40</td>
<td>4.00</td>
</tr>
<tr>
<td>Min</td>
<td>-0.50</td>
<td>-0.50</td>
<td>-0.40</td>
<td>-0.30</td>
<td>-0.70</td>
<td>0.00</td>
<td>0.00</td>
<td>0.40</td>
</tr>
<tr>
<td>SD</td>
<td>0.71</td>
<td>0.98</td>
<td>1.03</td>
<td>1.38</td>
<td>1.48</td>
<td>1.05</td>
<td>0.91</td>
<td>1.33</td>
</tr>
</tbody>
</table>

Abbreviations:
Delta: Temporal Temperature measured using temporal artery thermometer – Esophageal Core body temperature measured using esophageal temperature probe; difference between two temperature measuring methods
N: Total number of sample measurements collected sequentially
Mean: The average of difference in temperature for each measurement
Max: the greatest temperature difference observed during each measurement
Min: the smallest temperature difference observed during each measurement
SD: standard deviation- a simple measure of the variability or dispersion of a data set.

Limitations of the Study: A potential limitation of this practicum that has arisen during the protocol development is the limited selection of samples, since only those subjects who have esophageal temperature probes to measure core temperatures during the operations could be included in the study. Also, the patients who require Laryngeal Mask Airways (LMA) s in their esophagus during the operations were excluded from the study narrowing the selection. Many of the operations were either too short for sufficient data collection or the position of the subjects placed on the table during the procedures also limited the numbers of choices. Also, the usage of the Bair Hugger® warming system during surgeries was considered as one of variables on this study because the warming blanket seemed to interfere with measuring precise and accurate body temperatures using Exergen Temporal Scanner due to the warm air blown to the neck area. Sometimes, the surgical table was tilted toward the head direction for easier access for the
surgeons. As a result, blood would have rushed toward the head, thus, increasing the temperature of forehead on patients who had abdominal hysterectomy procedures. The manufacturer of the Exergen Temporal Scanner presumes that the highest temperature reading originates from the temporal artery. However, if the highest temperature reading occurs in an area remote from the temporal artery, the device will use that reading in the calculation of internal temperature (10). Therefore, blood rushing into the head region due to the head down tilt of the surgical table during some surgical cases could have prevented accurate measurements of temporal temperature using Exergen Temporal thermometry.

Another recognized limitation of this study design is that the anesthesia machines providers used to connect the esophageal temperature probe to the monitor to continually read the temperature during the operations were not calibrated properly for the study beforehand. Also, the depth of the esophageal temperature probe placed by each Certified Registered Nurse Anesthetist could have been different depending on the technique. In order to study the effect of Bair Hugger® on temperature measurements using the Exergen Temporal scanner, there should have been sufficient number of non Bair Hugger® cases for comparison, but only 4 non Bair Hugger® cases were available during the allotted time.

Finally, due to time limit of the internship practicum, only the correlation of temporal temperature and core temperature in an operation room setting could be studied. However, studies in a variety of settings other than the operation room, such as the emergency department, will be needed to further support the accuracy of temporal thermometry in critical settings when compared to core temperatures obtained by other methods.
CONCLUSION

The purpose of this pilot study was to evaluate the accuracy of temporal artery scanner when temporal temperatures were compared to core esophageal temperatures during the anesthesia induced surgical procedures. In order to assess the accuracy of the temporal artery thermometer, temporal temperatures were measured every 15 minutes using the Exergen Temporal Scanner during the surgical procedure and compared with esophageal core temperatures, which were monitored by anesthesia providers.

According to current results from this ongoing study, it was found out that temporal artery thermometry is not accurate within clinically significant levels when it is compared to core esophageal temperature. Based on the present data, it demonstrates that the temporal artery thermometer does not provide information that is an adequate substitute for core temperature measurement by an esophageal temperature probe. Especially, in an environment such as perioperative care, where precise temperature measurements are important, the temporal artery thermometer cannot be recommended as a sole accurate indicator of internal temperature. However, due to the limitations of the study design, further research with a better design may help to validate the accuracy of Exergen temporal artery thermometer. Also, data will be required to be pooled again for complete statistical analysis when the study is reevaluated.
CHAPTER III

INTERNSHIP EXPERIENCE

During the conduct of this study, I learned how to demonstrate good clinical practice skills while completing the internship practicum. Other training activities included Institutional Review Board interaction, aiding the study coordinators in other studies in every aspect including maintaining regulatory binders, documenting progress reports, reporting adverse events and maintaining accountability, completing case report forms, and developing recruiting skills and consenting skills. Also, I observed a site initiation visit, consenting process and study procedures.

The main objective of my internship practicum was to examine how developments made in the field of applied clinical research may translate eventually into the adoption of good clinical practices which will prove beneficial to human patients in real life situations.

At TREI, I learned what is involved in pursuing and conducting a clinical research study. I gained experience on how to submit IRB application electronically and I have learned that considerable time and efforts are needed to gain approval of a study by an IRB. I also have learned the importance of documentation and records keeping. Patience is very important in order to launch a study since many revisions, editing and making amendments are necessary. Privacy and confidentiality training was valuable and the protocol developing experience was challenging but rewarding.
Other tasks that I was assigned included: transferring source data into the case report form or electronic case report form after a visit was completed, maintaining a regulatory binder for my study, and maintaining accountability for the temperature log on refrigerators used to keep study drugs. Also, I observed and practiced the consenting process for the nurse glove trial, a product trial which compared two different latex gloves using a double-blinded method.

I also have learned how to develop the informed consent and other related forms including authorization to disclose health information and demographic forms for my project. I also assisted in preparing patient charts for the other studies conducted at the site. I have learned how important interaction and good communication skills are among the subjects and study staff.

**INTERNSHIP SITE**

The Research and Education Institute (TREI) for Texas Health Resources (THR) is one of Texas’ largest hospital systems. TREI is an independent and non-profit organization who is actively involved in conducting and coordinating clinical research studies across their 13 affiliated hospitals. The main research office is based on the Presbyterian Hospital of Dallas campus but trials may take place at any one of the 13 sites, including Arlington Memorial Hospital, Harris Methodist Fort Worth, Presbyterian Hospital of Plano, Harris Methodist Southwest, Walls Regional, and Harris Methodist HEB Hospital. The investigative site depends on the location of principal investigators for each study. The institute’s mission statement lies in conducting medical research, offering educational programs, and undertaking development projects that contribute to the prevention, diagnosis and treatment of disease (19). Currently, there are 10 different ongoing studies; an Alzheimer drug study, a Congestive Heart Failure Telemanagement program, a lower back pain treatment study, the XIENCE stent post approval
data collection study, a Chronic Obstructive Pulmonary Disease (COPD) drug study, 3 Gastric Esophageal Reflux Disease studies, a Nurse Walking Study, an Sequential Compression Device (SCD) sleeve Comparison study, along with my assigned Temporal Temperature Comparison project.

TREI for Texas Health Resources is actively involved in education and research with a current focus on continuing medical education and clinical research mainly on drugs, devices and registry data collections. TREI works to foster research and education, assisting and coordinating research and education efforts across the THR system. Their experience ranges from orthopedics, urology, oncology, cardiology, and neurology research and clinical trials to product evaluation, proof of concept testing and product development. Their ultimate goal is to advance patient care via translational research.

**INTERNSHIP DAILY JOURNAL**

**Week of August 25th**

**August 25th**

I toured around the Presbyterian Hospital of Dallas and the office area of the Research Education Institute within the hospital. I was introduced into the basic skills of Outlook email and calendar systems through the computer orientation. I shadowed the recruiting process for the nurses, who can participate in the gloves trial in ICU, OR, and ER during the afternoon. I went to the security office to obtain the ID badge and the parking pass. Went over the Research Privacy Training packet and signed the form, which was turned in to Laurie Comeau, my mentor at this internship site.
August 26th

I came to Presbyterian Institute for Minimally Invasive Technology in the morning to help with the gloves product trial. Went to the security office to resolve the parking badge problem and turned in the requested parking form. Also, called the Help desk to get my password to get into MyLearning program for the training purpose, but then it was not ready yet. They instructed me to wait so I worked on signing up for the electronic IRB account. I checked the emails and the schedule for this week and next week. I sat at the receptionist desk to assist them with the signing in procedure. I went over the sample informed consent form and read my study related articles in the Temporal Thermometry Study binder. I helped running the glove trial with the nurses and went over the informed consent form signing process with each participant. I got to observe how the product trial runs and the nurses answered me the questions I had about the study they were doing. It was a good experience.

August 27th

I came to P.I.M.I.T in the morning to continue the glove product trial. I was going over the informed consent with the subjects and helped them getting ready for the trial after sign-in. I screened the subjects to see if they meet the criteria described for the study. Laurie, my mentor showed me the downstairs of P.I.M.I.T where they do the experimental animal studies and also surgeries. I got to meet the nurses who work there and they would allow me to observe the surgeries in the near future. I looked around the downstairs and came up to work at the front desk. Laurie showed me around the electronic IRB website and taught me how to start up the IRB process. Also, she showed me the L-drive where I can access all the study related documents for TREI. I worked on the eIRB study start-up procedures for about 2 hours with as
much as information I had. I helped with the glove product trial rest of the day, doing
consenting, checking-in and screening. I observed Nicole Richter, my associate clinical research
coordinator at this internship site, make the dried ice for the specimen, and prepared and shipped
off the specimen for her study. I came back down to P.I.M.I.T and worked on my study eIRB
application on the computer until I left.

**August 28th**

I checked the emails and the schedule and then worked on MyLearning, which is the HIPPA
privacy and security training online program for new employees at Texas Health Resources for
about two and a half hours. I read over the partially developed protocol for my study and started
to work on developing my own informed consent form using a template downloaded from the
eIRB website. This process was very time-consuming and tedious but it was a review
opportunity for me to go over each elements of an informed consent form. It was a great
opportunity for me to learn how to develop your own informed consent form before you start the
study. I emailed Dr. Gwirtz and Dr. Aschenbrenner any updates on my status.

**August 29th**

I came to work at 8 O’clock in the morning and checked the emails and the schedule for today.
I went down to the employee health center to get the varicella titer done. We had a staff meeting
and discussed about the current updates on all the ongoing studies, number of subjects enrolled,
number of screens, advertisements for the studies and IRB issues. It was helpful to get an idea of
what takes a place at this site currently. Laurie instructed me to work on my informed consent
form until I get to meet other principal investigator nurse sometime next week to finalize the
protocol. I will have to finish submitting the THR IRB application by the following week and start to work on submitting my school IRB application afterwards. I worked on revising my informed consent form for the study and had Nicole proofread it. My informed consent form is written in 9th grade level language so I now have to bring it down to 8th grade level. I learned how to keep a temperature log for each fridge used to store the study drugs and this will be done as one of my daily job duties from now on. Nicole showed the examine rooms and how to use the medical equipments. I worked on revising the informed consent form rest of the day.

Week of September 1st

September 1st

Out of office for a holiday

September 2nd

I came into the office and checked the emails and schedule for today. I worked on MyLearning online HIPPA training program for additional trainings on privacy and confidentiality for about 2 hours and finished all the required modules. I checked the temperatures on the refrigerators for the ongoing studies at this site and logged them on the temperature log sheet. I have uploaded the CVs and the NIH training certificates on human subject protection and research privacy for everybody on my study into my computer and made a copy for the school. I went to the electronic IRB site and uploaded required CVs and other documents for my study. I also worked on editing my eIRB application for about 1.5 hours. I started to develop the “Authorization to use or disclose protected health information for research” form for my study. Nicole helped me
with proofreading and I needed to have Laurie finalize it for me. I developed the criteria form for the study until I left.

**September 3**

I finished working on the criteria form for my study and did the temperature log on the fridges used for the site’s studies. I worked on the case report form and the demographics form for my study using the Microsoft Excels for about a couple hours. I printed out all the documents I had been working on and prepared the questions to ask the principal investigator, Leslie Rodriguez about the protocol development teleconference meeting at 10 AM, but then it was cancelled due to his busy schedule. We will try to have the conference regarding my study on Friday. Laurie, my mentor explained to me about the biostatistics I will be using for my study and we went down to P.I.M.I.T to go over the possible choices of the statistical tests I can use for the study. During the afternoon, I made the patient charts for Nicole’s studies for about 2 hours. Laurie taught me how to use the oral electronic thermometer and the temporal scanner. I started to fill out the UNTHSC IRB application and the conflict of interest form after checking out the school IRB website. I emailed Dr. Gwirtz with the questions and called the school IRB office to help me with filling out the IRB forms. Laurie talked to me about the scheme for my study and I started to make adjustments on the informed consent form and eIRB application to add Dr. Gwirtz as a co-investigator. I got Dr. Gwirtz’s curriculum vitae and the CITI training record certificate ready for my study. I helped Nicole to carry the equipments for her study tomorrow to her car.
**September 4th**

I came to work and checked the fridge temperatures for the studies at this site. I checked the emails and the schedule for today. Laurie, my mentor went over all the forms required for the study with me and made corrections and adjustments. We also emailed those forms to Leslie Rodriguez who is a principal investigator for this study and asked him to go over them to make corrections. Laurie instructed me to make a section in the binder for correspondence, which I will collect all the incoming and outgoing emails regarding this study. I worked on revising the case report forms such as temperature log for data collection and progress notes. It was a good experience for me to review the Microsoft Excel software. I made a sample patient chart with all the updated forms needed for my study.

Laurie and I worked on the eIRB application for my study and made a few revisions for a couple hours. I also downloaded the BillNo1 form from eIRB website and filled it out because the completed and signed BillNo 1 form is a part of the requirements for eIRB application submission. I printed the partially filled out BillNo1 form to obtain the signature from Leslie Rodriguez tomorrow during the meeting. I emailed Dr.Gwirtz with the status and IRB Texas Health office with a question. I worked on revising my eIRB application with help of Nicole rest of the day.

**September 5th**

I checked the temperatures on three fridges used for the studies at TREI and checked the calendar for today’s schedule. I checked on the status of my eIRB application and the problem I had on page 6 about grant section has disappeared. Laurie, Nicole and I had Promise training, which is required to have once month to enhance our work ethics and behaviors being in the
clinical research field. Also, we had a staff meeting to discuss any updates on the current
studies. Laurie mentioned about my possible role as a non-study person in Nurse Walking Study
in the near future.

I got to learn how to assess E.C.G and how to draw blood, which I will not perform myself on
patients due to the school policy. Also, I learned how to make slides with blood and to measure
the vital signs such as weight and height. It was a very good and exciting experience for me,
which I can utilize definitely.

I added Dr. Gwirtz, my major professor to my eIRB application successfully. I and Laurie were
supposed to have a tele-conference meeting with Leslie Rodriguez, the principal investigator for
my study at 2:00 PM but he was busy at that time again. The conference got delayed to some
other time. After discussion with Laurie, we changed the plan on our protocol. I have worked
on revising all the forms that had been developed for my study rest of the day.

**Week of September 8th**

**September 8th**

I checked the temperatures on fridges used for the studies and checked the emails. I have
received the email with some helpful information from Exergen whose temporal scanner we may
use for my study. I revised the BillNo1, a requirement for eIRB submission and emailed back
Exergen requesting more information. I talked to Laurie and Leslie on the phone to touch-base
with them regarding the study. At this point, I can not proceed further because I will have to
decide which temperatures I want to compare for my study and make corrections again on the
protocol and the related forms. I read the related literature, which was faxed over by Leslie to
help me with this decision.
I worked on going over the protocol and the informed consent form for the stent study they have going on at this internship site so that I may be able to help with the consenting process. I also went over the heart failure study protocol and its informed consent form. It was a good experience for me to get a clearer idea of what elements should be included in an informed consent form and a protocol.

**September 9\(^{th}\)**

I logged temperatures on three fridges used for the studies at the internship site and I checked the emails. I reviewed the literatures all day in my study binder, which I may be able to refer to when writing the proposal or background section on the protocol.

**September 10\(^{th}\)**

I checked the temperatures on the study fridges and logged them on the temperature log sheet. I checked the emails and the schedule for today. I received the requested device classification documentation from Exergen and prepared BillNo1 for my eIRB application. I also received the documentation for the device price, which is another requirement for BillNo1. Exergen has informed me that I will be able to use any of their diagrams for my publication after I specify to them which one I will want to use.

I communicated with Leslie Rodriguez on the phone to ask him the study related questions. Our plan has changed so I worked on revising the protocol for my study. I also have changed the criteria on inclusion and exclusion criteria and revised the informed consent form sparingly. I worked on writing the background section on the protocol referring to the literatures I read.
**September 11th**

I did the temperature log on the fridges for the site studies, which is one of my daily duties. I went to RefWorks website and went over the tutorials to utilize the software for easier citation when writing. Laurie and I discussed about the protocol how we can improve it and what other information we needed. I made the cover page for my proposal and emailed Dr. Gwirtz to ask how to write the summary section effectively.

After Lunch, Laurie instructed me to revise the protocol slightly and also emailed Leslie Rodriguez to look over the protocol to suggest any necessary changes. Laurie also wanted me to add the bibliography section on our protocol so I used RefWorks to create the bibliography with the references we had in my study binder. I completed adding the bibliography section at the end of the protocol successfully using RefWorks and I was very glad that I got to learn how to use this convenient software. I practiced how to use the software more effectively rest of the day.

**September 12th**

I went to Arlington Memorial Hospital to meet up with Laurie and Nicole at 10:00 AM to attend the site initiation visit for the stent study. I got to meet other study staff on this study and learned how the clinical studies get initiated. Beth Rose, senior clinical research associate from Covance who runs the clinical research for Abbott for this particular study gave us presentations about how to conduct the study appropriately and went over how to fill out the documentations electronically. Questions were answered and Nicole went over the informed consent form for this study.

I came back to the PHD office after the meeting and checked the temperatures on the fridges for studies. I checked the emails and received the slightly revised protocol from Deborah Behan.
who is a co-investigator on my study. I called Deborah to discuss about the study and she wanted to find out exactly how many subjects are needed for the study. Leslie Rodriguez agreed on the latest version of the protocol. Laurie and I went down to PIMIT to use the wireless laptop which has Sigma Stat software to figure out the statistics. Laurie and I figured out the subject number needed for this study and set the power up to be 0.9 on this study. We will have to get agreements with Les and Deb and go from there. It was a good experience to learn how to do the statistics to figure out how many subjects needed for the study depending on how accurate the result should be. I worked on revising all the forms related to the study.

**Week of September 15**

**September 15**

First, I did temperature checks on the fridges used for studies and checked the emails and schedule for this week. I have reviewed the articles faxed over by THR library, and filed the corresponding documents in the study binder. I emailed the principal investigators with the updates and asked for their approvals on the protocol. Laurie, my mentor gave me statistics for my study and I worked on revising all the forms to be updated. I also worked on revising all the information on eIRB application for Texas Health Resources. Laurie and I discussed about the upcoming schedule relating to my study and I also had Laurie and Nicole sign the Conflict of Interest form for my school IRB. I went down to PIMIT to enter the data for Nicole’s heart failure study into the software program on one of THR laptop. I made patient’s study charts for the stent study, which we need for consenting process tomorrow at Arlington Memorial Hospital.
**September 16th**

I went to Arlington Memorial Hospital to meet up with Nicole at 8:00am and I and Nicole went to the Cath Lab holding room to look for the potential participants who could be candidates for the stent study. After we interviewed some possible candidates who were about to go into the surgeries, we found one that might be a good candidate for the study. I watched Nicole consenting the patient and the wife. After we were done with recruiting patients for the stent study, we went to Heart failure clinic to consent the patients for the heart failure study. Two subjects showed up at the clinic and I helped the one of the patients filling out the paper works. I watched consenting process and it was a valuable experience. I also helped Nicole with filling out the forms in the charts and wrote the progress notes. Nicole instructed me to enter demographics and medication list of those patients we consented today into Pharos system, which is used to keep up with data retention and progress of patients’ daily log. Entering the medication list into the system was time consuming because we had to look for the right one in the drop down box and go through each list of medications categories. However, I learned many different medications used for the heart problems and hypertension. We assigned the study number to each subject and recorded them in the charts.

**September 17th**

I logged the temperatures of the study fridges on the log sheet and checked the emails and schedule for today. I prepared the documents that need to be signed by Leslie Rodriguez because we are visiting Harris Methodist Southwest Hospital today. I also read the article about stents and some medications so that I can be familiar with the stent study they have going on at this internship site.
Laurie, Nicole and I went out to HMSW to visit Leslie Rodriguez to discuss the study and toured the hospital, pre-op area and the OR, where my study will take a place. Upon the discussion we had regarding the study, the protocol will have to be changed again. I was introduced to the nurses and Laurie showed me what I will be expected to do. We went to Wal-Mart to shop for scales used for the heart failure study but could not find the right one. I came back to the office and revised the protocol slightly. I printed out the emails that were filed under the correspondence section in the binder. I worked on revising all the related forms regarding my study, and Laurie and I had a discussion about the study. She mentioned that I will need to be more assertive and confident delivering the messages to patients, which I will have to learn eventually. She also instructed me to go to the University tomorrow and figure out the sample size needed for my study using the resources available. The sample size Laurie had figured out last time was incorrect. I emailed the professors for help.

September 18th
Out of office- at the university working on the statistics calculations for my temperature study

September 19th
Out of office –at the university working on the statistics calculations for my temperature study

Week of September 22nd
September 22nd
I did the temperature log on the fridges and checked the emails. I also looked at staff meeting guidelines, which was on last Friday. I also updated my schedule and filed the corresponding
files in the study binder. I have forwarded the email from Dr. Le, a biostatistician to Laurie for approval of the sample size for my study. I prepared the forms for Teresa Turbeville to sign, who is going to be my new mentor after Laurie leaves for a new job. I faxed over the conflict of interest form to be signed by Deborah Behan, one of study co-investigators. I emailed Dr. Biswas, a biostatistics professor at UNTHSC for help on the sample size determination. Laurie gave a tour around the PHD operating rooms so that I would be familiar with the setting where I will be working to collect the data for my study. I worked on revising the related forms for my study and also on eIRB application. I emailed Teresa to send me her CV so that she can be enlisted as study personnel on my study. I went to XIENCE stent study training website to be trained for the study. I went to school to meet up with Dr. Biswas in Public Health department to get help on my study statistics. Dr. Biswas was very helpful to direct me to use the appropriate statistical analysis such as Concordance correlation, which will give us a better understanding of the study results. I discussed my study statistics with her for about an hour.

**September 23rd**

Temperature log on fridges were done in the morning. I read an article about how to appropriately assess statistical analysis when comparing two different methods to reach the agreement. I finished XIENCE training modules and obtained the certificates, which were filed in the study binder. I registered for the CPR basic life support class, which is a requirement at the internship site and it will be on October 10th at Harris Methodist Fort Worth hospital. I worked on writing the proposal.
September 24th
After doing the temperature log on the study fridges in the morning, I worked on writing the proposal all day. I had Laurie Comeau; my current mentor proofread it for me.

September 25th
I met up with Nicole, a clinical research coordinator at TREI at Arlington Memorial Hospital at 8:30 AM and went to Cath Lab pre-operative area to look for the potential candidates for XIENCE stent study. We found a lady who showed interest, so Nicole consented the patient while I was observing. Then, we went to Heart Failure clinic in Arlington Memorial Hospital and went through the charts with a study nurse to look for the possible subjects who could enroll in AT&T heart failure study. We obtained a list of possible candidates for the heart study and came back to PHD.

I did the temperature log on the study fridges and reviewed the literature related to my study to find out what type of statistical analysis other people had done on their similar studies. I also emailed Dr. Biswas for help to calculate the sample size for my study with Bland and Altman approach. I also helped Nicole writing the progress report on a subject who signed the informed consent form today at AMH.

September 26th
Temperature log on the study fridges was done and I emailed a few professors at UNTHSC to get some help on the sample size statistical problem. I searched the web and reviewed some articles to learn how to do statistics on subject sample size but I could not find much. I reported to Laurie what I had so far and indicated that I am planning to use Bland and Altman analysis
and Pearson “r” coefficient correlation for my study analysis. Laurie agreed and also commented me to use the paired t-test also. We went down to PIMIT to use the laptop with Sigma Stat software and played with it to learn how to use it for analysis later. Laurie confirmed on the sample size to be 50 subjects on my study using paired t-test and had Teresa, the director at TREI to provide me with a biostatistician to analyze the data for me later in the future.

I worked on revising the protocol to reflect the additional information on statistic section and emailed to Laurie to approve and send it to Leslie Rodriguez and Deborah Behan to finalize it. I also helped Nicole to put the informed consent forms together for Nurse walking study for next Monday through Wednesday at Presbyterian Hospital of Plano.

I practiced consenting with Nicole for XIENCE stent study and revised eIRB application slightly. I worked on filling out the school IRB application for submission.

**Week of September 29th**

**September 29th**

I went to Presbyterian Hospital of Plano at 6:00 AM to help with Nursing Walking study consenting. I volunteered as non-study personnel to make sure there was no coercion involved when consenting participants. We recruited the nurses from ICU and 5th floor unit in building A. Nicole showed me how to fill out the expense form for gas compensation; for the mileages from PHD to PHP, I will be eligible to receive. She also showed me how to make amendments on the approved IRB application.

We made copies of those informed consent forms and gave it back to each subject who signed up for the study after the principal investigator and the study coordinator signed it.
**September 30th**

I came to PHP at 7:00am to help with nursing walking study. Nicole had a nurse at 5A sign the informed consent form. I worked on revising the proposal and the informed consent form for my study, which was revised by Dr.Gwirtz. Laurie approved the revised version of protocol and it was sent to the study staff to finalize it. I uploaded the revised version of informed consent form and protocol onto eIRB. I emailed the revised version of the proposal back to Dr.Gwirtz and she wanted me to send it to all the committee members to approve it.

I made the copies of the signed informed consent forms for Nurse walking study and dropped the copies off at nurses’ mail boxes. I kept the originals to take it to our TREI office to file it in the study binder.

**October 1st**

I went to Harris Methodist Southwest to attend the EPIC training course at 8:00am. However, Leslie Rodriguez stated that I did not have to take this particular course because I do not have to place orders and enter the data into the patient chart system to conduct my study. Laurie instructed me to go to Arlington Memorial Hospital to work on school assignments and to update my eIRB application with any new information. Also, I was told to clock in and out starting from tomorrow since it is a requirement for contracted workers.

**October 2nd**

I logged the temperatures on the study fridges and checked the emails. I printed out the emails that needed to be filed in the study binder under the correspondence section. I filled out the
expense report for September and had Laurie sign off. Laurie took me downstairs to show me how to clock in and out everyday but my badge did not work properly.

I updated the eIRB application for my study with the revised forms of informed consent form and HIPPA form, which now has Dr.Gwirtz’s name as one of the co-investigators. I cleaned up the desk drawer files accordingly into the appropriate folders. Laurie signed the research proposal submitting form and she left for a new job. I went to Dr.Lipton’s office with Nicole to observe the study visit procedures and it was interesting to watch a patient with Alzheimer disease perform the mini-mental state test. I watched Nicole collecting vital signs and filling out the procedural notes. It was a good experience for me to learn how the study visit is done. After I came back to the office, I watched Nicole entering the data from the Alzheimer study at Dr.Lipton’s office into the Interactive Voice Record System; electronic registry system. I also helped Nicole making a binder to keep all the signed informed consent forms from Nurse walking study at PHP. Deborah Behan, one of the study staff approved the protocol and now, I am waiting on Leslie Rodriguez to finalize it. I resolved the badge issue with the security office and now, I am eligible to clock in and out everyday. Teresa Turbeville, my new mentor has sent over her NIH training certificate for me to turn in to UNTHSC IRB. I spent rest hours revising the proposal reviewed by Dr.Aschenbrenner, one of my committee members at UNTHSC.

October 3rd

I went to Harris Methodist Southwest hospital education center for EPIC training, which I need to access the medical records of patients at HMSW for my temperature study. Leslie Rodriguez, the instructor explained well how to use the computerized patients’ records properly. After the
EPIC class, Leslie and I had a short discussion about our study and he stated that he will review the protocol and get back with me soon.

**Week of October 6th**

**October 6th**

I clocked in and came to the office. I did the temperature log on the study medication storing fridges and checked the emails. I have submitted the school weekly journal from last week to Teresa Turbeville, my new mentor who replaced Laurie Comeau’s spot. I worked on developing the protocol synopsis for UNTHSC IRB to review and also prepared school IRB required documentations along with the IRB application for hours. The UNTHSC IRB application and additional required documents were ready for submission at the Office of Protection of Human Subjects after Dr.Gwirtz’s approval.

I created the power point materials that will be used for in-service among the medical staff at HMSW before my study begins. I clocked out for today.

**October 7th**

Temperature log and email check were done. I and Nicole cleaned the examination room and threw away all the expired medical supplies and lab kits. We also tossed out the sharp containers that were full down at P.I.M.I.T. Nicole proofread my in-service power point slides and I revised it. I went to UNTHSC to meet up with Dr.Gwirtz to discuss about the IRB application and the required additional documents. After Dr.Gwirtz approved the IRB application, I went into the Office of Protection of Human Subjects at UNTHSC to submit the hard copies of all the required documents along with IRB application. They said that they will contact me or
Dr. Gwirtz for any problems with my IRB application. I also had Dr. Gwirtz signed the proposal form after obtaining the verbal approval. She gave me a hard copy of my proposal to turn in at Graduate School of Biomedical Sciences and I dropped off the proposal form at Dr. Aschenbrenner’s office for him to sign if he approves it. His office contacted me later to notify me of his approval and the form was ready to be picked up. My proposal was approved by all the committee members and now, it is ready to be turned in and filed at the GSBS office at UNTHSC.

October 8th
Out of office

October 9th
Temperature log on the fridges containing study materials was done and email check was done in the morning. I electronically submitted the Conflict of Interest form for Nurse Walking study indicating that I do not have any financial interests related to the study. I called Leslie Rodriguez to check on the status of the protocol and he said that he will read it today and let me know. He will call me back today.
I put all the study documents together and made Xience study charts for later use.

October 10th
I went to Harris Methodist Fort Worth Hospital at 8:30am to participate in CPR complete course, a class of Basic Life Support. It was an all day class of 6 hours long. I have learned how to perform CPR in adults, children, and infants as well as the Heimlich maneuvers. I took the
assessing test and passed it. I obtained the certificate in CPR. I went to school afterwards to pick up my proposal from Dr. Aschenbrenner’s office and turned in my proposal to the GSBS office. I also turned in the new committee member form along with the degree plan form and notified the GSBS with a change of one of my committee members.

**Week of October 13**

**October 13**
Temperature log and email check were done. I completed the online after training survey for Xience stent study. I emailed Teresa Turbeville my last week’s journal for her to sign off. I was still waiting on Leslie Rodriguez to finalize the protocol so that I could submit it to the IRB. I observed Nicole, a CRC, entering the information into the electronic case report forms online and helped Nicole filling out the concomitant medication list. I and Nicole went to the exercise lab across the street to pick the Chronic Obstructive Pulmonary Disease study supplies, which they did not need any more. Nicole also showed me how to request IRB to continue the review on a study, which has been ongoing more than a year. I learned that the IRB approval is needed every year to continue the studies and we even need to notify IRB with the cases of discontinuation or completion of studies.

**October 14**
Leslie Rodriguez replied back to me stating that he was waiting on CEO of HMSW to sign on BillNo 1, which is a part of IRB application. I printed out the email and filed it in the correspondence section of the regulatory binder. I broke down the study charts for COPD study, which is no longer available for enrollment at this site since it is closed due to the overall number
of participants filled up to the requirement of the study. I threw away all the source documents in the shredder box and saved the charts.

I emailed all the study staff on my project the study related materials including informed consent form, HIPPA form, inclusion/exclusion criteria and case report form upon the request of Leslie Rodriguez, the principal investigator on my project. Nicole reviewed the materials and I revised the informed consent form slightly according to her suggestion. I made sure that the informed consent form is still written in 8th grader level of English. I also revised the other forms as well.

October 15th

Routine daily activities such as temperature log and email check were done. I uploaded the newly revised study forms for my study on electronic IRB. I filled out the gas expense form for October and I watched Nicole making amendments online for one of her studies. I organized all the outgoing and incoming emails into the different folders. I helped Nicole by making the data collection binders for Nurse Walking Study at Walls Regional Hospital. I finally received the email from Leslie Rodriguez with all the revised forms attached. I looked them over to make changes according to his suggestions and send them back to Leslie for finalization. I uploaded the BillNo 1 onto eIRB with my signature on it along with the other revised study forms. I also emailed IRB staff to fix a problem for me on my application, because it had more than needed documents uploaded on one section. I asked her to remove inclusion/exclusion criteria and temporal scanner instruction sheets. I reviewed all the information thoroughly on eIRB application before I emailed Leslie to notify that it was ready for him to submit as a principal investigator. I made a sign in sheet for Nurse Walking study using Excel.
October 16th

I met Nicole at AMH at 6:30am for the XIENCE stent study consent procedure. We recruited one patient who was willing to participate in the study and had him sign the informed consent forms after reviewing it with the patient. We made a copy for the patient and a copy for their hospital chart. I came back to PHD TREI office and did the daily routine temperature log and email checks.

I prepared all the equipments we need for Alzheimer study at Dr.Lipton’s office today for one patient. I and Nicole went to go see this patient who was having a visit # 6 at Dr.Lipton’s office for Alzheimer study and assessed the patient’s vitals. The patient took the MMSE test, which is a mini mental state exam that Psychologists perform to determine the mental functionality and to see if the condition became worsened. The caregiver answered the questionnaire and patient passed the test. Nicole dispensed the continuing study medication to the patient. It was a valuable and exciting experience. We came back to the office and I put the supplies back to where they were. I also entered the patient’s visit data such as new concomitant medication and adverse events into IVRS system and sent it to the sponsor electronically. I learned how to report the adverse events for this study. I faxed over the EKG result for one patient to Dr.Lipton’s office and dropped off the study contract to Teresa Turbeville to sign upon Nicole’s requests.

Leslie finally submitted his conflict of interest form on eIRB and submitted the IRB application for my project as a principal investigator. It has already approved on scientific merit and feasibility part by THR and it will be reviewed in an expedited manner. At this point, I will just wait THR IRB to approve my application after reviewing.
October 17th

I met up with Nicole at 8:00am at AMH again to look for the potential participants for Xience stent data registry study. One patient stated that she was not interested to be in the study and the other one did not meet the criteria because of her language spoken. I and Nicole went to the heart failure clinic to look for possible candidates for AT&T heart failure study and the nurse, Terry helped us reviewing the charts. I came back to PHD office and did the daily routines. I helped Nicole making labels for Xience study that goes on patients’ charts to indicate whether the patients signed up for the study. I observed Nicole uploading the angiogram of a patient for Xience study.

Week of October 20th

October 20th

I went to Walls Regional Hospital in Cleburne by 6:00 AM to recruit nurses for Nurse Waking study. I watched Nicole consenting the nurses at ICU and Med-Surge after reviewing the informed consent form and answering the questions. I came back to the PHD office and did the daily routines.

I made the binders for the signed informed consent forms for Nurse Walking study at Walls regional hospital and Harris Methodist Southwest Hospital, and I filed the consent forms from Walls regional into the corresponding binder. I made some envelops with addresses to go out with the gift cards for the participants for Nurse Walking study as compensations.
October 21st

Daily routines were done and I checked eIRB for any update on the status. It was in the process of reviewing by the departmental reviewers. I filed new updated inclusion/exclusion criteria sheets in the study charts for Gastro Esophageal Reflux Disease study and discarded the old ones. I made some more envelopes for compensations on the participants for Nurse Walking study. I made some more copies of the informed consent forms, which we need tomorrow at Walls Regional Hospital in Cleburne. We had a monitor visit for Alzheimer study and the monitor looked over the study charts and records. I put all the study charts back to where they were after the monitor visit was done. I scanned all different versions of the informed consent form for Rao’s study so that Nicole could upload them on eIRB.

October 22nd

I went to Walls Regional hospital in Cleburne by 8:30 AM to consent more day time shift nurses for Nurse Walking Study. I and Nicole went to ICU and Med Surge and had 5 more nurses to sign the informed consent forms. I dropped off the copies of the signed consent forms from Monday at their mail boxes accordingly. I drove back to PHD office and did the daily routines. I checked on the status of my eIRB application and it was approved by the department and sent to IRB for review. I read the protocol for Alzheimer study by Novartis to get familiar with it.

October 23rd

Daily routine was done in the morning and I attended the site initiation visit by a monitor from Eisai pharmaceuticals for Gastro Esophageal Reflux Disease study. It was helpful for me to learn how the study gets initiated and I was able to become familiar with this particular study. I
and Nicole went to the office of Dr. Jain who is the principal investigator on the study, and went over the study with the monitor.

I cleaned out my desk for the nurse who will start to work at TREI on next Monday. I sent out all the compensation mails to the participants for Nurse Walking study at PHP and Walls Region. I also called the people on a list from the senior clinics at PHD to look for potential subjects for AT&T heart failure study and 9 out of 53 said that they were interested. I called the subject on Xience stent study for 30day follow up but the subject did not answer. So I left her a message to call us back and documented the call on the progress note sheet in the study chart.

I met Dr.Persley who is a sub-investigator on GERD study and had her sign the COI form.

October 24th

I met up with Nicole at AMH at 9:00am to recruit potential subjects for Xience stent study but no one was interested to participate in the study. I came back to PHD office and did my daily routines. I called the people on the list from the senior clinics who did not answer my calls yesterday to see if they wanted to participate in AT&T heart failure study. Some of them said that they were interested and others did not want to.

I got an email from Dr.Gwirtz stating that school IRB wanted some more information on my protocol regarding the delegation of responsibilities. I revised the protocol accordingly and sent it back to her on a timely manner. I also received an email from Deborah Behan at Harris Methodist HEB hospital stating that they would like to join the temperature study. I will need to create an addendum to my eIRB application; however, I will need to wait until the initial study review will be completed. I will need to revise all the study related forms to reflect the changes of locations. I let Deborah know that I will be working on this next week.
Week of October 27th

October 27th

I met up with Nicole at Walls Regional Hospital in Cleburne at 6:30 AM to distribute the pedometers and to consent for some more nurses who were not present last two times we visited. Dr. Pati, the principal investigator came along and we all took pictures. I dropped off the copies of informed consent forms at the mail boxes for nurses who had signed them on our last visit. Nicole explained how to use the pedometers and how to log in. I came back to PHD office and did my daily routines. We have a new manager, Skip Barnes starting today. I emailed Deborah Behan back stating that the addendum will not be added to the study until the initial review will be completed. I worked on revising all the study related forms to add HEB. However, I needed more definite ideas about how many subjects at each site we need and what the names and responsibilities of new additional people are. I emailed Leslie Rodriguez and Deborah Behan to reply me back.

Dr. Gwirtz sent me back the school protocol synopsis with changes and instructed me revise it according to HSC IRB suggestions. I worked on revising the protocol and send it back to Dr. Gwirtz with the significant changes. THR IRB approved my study without any stipulation requirements. It was a very exciting moment for me and I printed out the approval letter to file it under the study binder. I created the addendum amendments onto eIRB to add HEB staff and new site as well as my new manager, Skip Barnes on my study. The informed consent form and HIPPA form were stamped by IRB, however, I need to revise them with the “track changes” to add HEB as one of the sites. I started to work on revising the forms.
October 28th

I went to AMH by 7:00 AM to look for the possible subjects for XIENCE stent study and I consented one of the patients at Cath Lab holding room. I and Nicole also walked around the hospital consenting some in-patients who showed the interest of participating. We made one copy of the informed consent form for the patients and one for the hospital patients’ chart. I came back to PHD office and did my daily routines. I got an email from Leslie Rodriguez stating that his job position was eliminated from HMSW. If he finds a job within the system, he will remain as a principal investigator on my project. However, if not, a replacement will be necessary. This was a big shock for me and as of now, I will have to check with Leslie what the plan is. I left a message for him to call back to show me the direction. Dr.Gwirtz wanted me to send her the informed consent form with revision so I sent it back to her after revision. I emailed Dr.Gwirtz with the updated status on my project. I made some envelops for AT&T heart failure study where I am sending out the informed consent form for the possible subjects to read over.

October 29th

I came to PHD office and did the daily routines. I got an email stating that UNTHSC granted an approval for me to start to study since the protocol and the ICF had been approved. It was good news, but I have to make an amendment to reflect the additional new people on the study from HMHEB and to list HEB as an investigation site. I looked through the OPHS website to obtain helpful information. I emailed Dr.Gwirtz to teach me how to make an amendment for the school IRB. I worked on making changes on THR protocol to have HEB as one of investigational sites and also incorporated all the changes that were requested by school IRB into the THR protocol. I left a message for Leslie Rodriguez to call me back to tell me what he wanted me to do at this
point. I can either start the study at HMSW, which had been approved already by UNTHSC and THR, or wait to make an amendments adding HEB and to get approval. I revised the ICF as well accordingly.

I wrote up the progress notes in the study charts on 8 subjects who agreed to participate in XIENCE stent data registry study but ended up not getting enrolled in the study due to screen fails. If the patients signed the ICF and did not receive the XIENCE stents during the surgery, they were considered as screen fails. I organized the XIENCE study charts in the shelf, where we keep all the current study binders at this site, by a study number sequential order. I sent Skip Barnes an email notification to turn in his COI form for THR and UNTHSC.

October 30th

I came to PHD office and did the daily routines. I called Deborah Behan to touch base with her and she stated that the study staff at HEB was not fully developed yet. Also, she said that some of the new people added to the study still need to complete the NIH or CITI training. I let her know that I am in the process of making an addendum so I will just wait until they are ready with a complete list of new study staff for HEB. Leslie Rodriguez revised the in-service power point materials for me, and would let me know when I can start in-servicing and collecting the data after he meets with Certified Registered Nurse in Anesthesia at HMSW. Deborah Behan looked at the in-service material and made additional changes on it. I called back some potential AT&T heart failure patients who had not answered the phone calls last time. I emailed Leslie Rodriguez to request an account for me to access medical records at HMSW since my study was about to begin. Skip Barnes assigned me to help him with pre-screening procedure for one of his studies about an investigational anticoagulant drug.
October 31st

Daily routines were done. Skip asked me to start to help him with pre-screening procedure for one of his studies. He went over how to do it according to inclusion/exclusion criteria and gave me a list if people who were admitted to ER at PHD. I am going to be doing this task as one of my daily routines from now on. Skip looked at EPIC (electronic medical records at PHD) to look closely if the ones who had been pre-screened by me, met other criteria.

Week of November 3rd

November 3rd

Daily routines were done including pre-screening job for Skip’s drug study. I prepared the equipments needed for one of the subjects’ visits in Alzheimer study, who is having visit #7. I called back the potential AT&T heart failure monitor study subjects who had showed interests in participating to see if they had received the information packets regarding the study in the mail and they still wanted to participate in the study. One person wanted to be on the study so I set up the appointment for her to come in and sign the consent form at our office.

I and Nicole went to Dr. Lipton’s office to do the study procedures for the subject who was having visit #7. I measured the vitals of the subject such as heart rate, blood pressures, and weight. The subject took the MMSE test given by Dr. Lipton and she did not decline. So, Nicole distributed the continuing investigational medication to the subject’s caregiver and set up an appointment for next visit.
November 4th

Due to Nicole’s absence from having a cold, I had to call the patient who was supposed to come in today to Dr. Lipton’s office for his first visit, and rescheduled his appointment. I also called Dr. Lipton to notify the situation and she removed the appointment from today’s schedule. I pre-screened the yesterday’s list of patients at the Emergency Room at PHD according to the inclusion/exclusion criteria for Skip’s drug study. I emailed Leslie Rodriguez to touch base with him on my temperature study.

November 5th

Daily routines were done and I got an email from Leslie Rodriguez today. He spoke with the chief anesthetist at HMSW and found two major concerns on my protocol about the temperature study. One, on patients that have the esophageal probes during operations, the Bair Hugger warming system goes over the patient’s head and creates a tent and thereby traps heated air around the patient’s forehead. Two, a Bispectral Index System monitor is used during the procedure (this measures anesthesia levels during surgery) and the strip goes across the area that we will be measuring. I will have to look into this and resolve the problems before I can start the study. Also, they wanted me to add the SRNAs in this project so I will have to add them to the research team. I emailed the committee members about this frustrating situation and also emailed back Leslie stating that I do not know what to do at this point. I tried to do some research about this ordeal but could not find much information that could be helpful. I spoke with Skip about my study and he told me to call the manufacturers to send me some literatures. He also helped me with the direction. I contacted the company who makes BIS and requested some information to be sent. I read Exergen instruction sheet and converted the
thermometry from reading Fahrenheit to Celsius for my study data collection. I also emailed Exergen with questions regarding the temperature study and also requested some literatures.

November 6th

Daily routines were done and I emailed Dr. Gwirtz with updates on my study. I read some literatures sent by Exergen, which was helpful. I emailed back Exergen with some more questions regarding the issue occurred on my study. Skip Barnes recommended me to write an email to Dr. Thomas Shires who is a chief of surgery here at PHD to ask for some help on my situation. I wrote him the email asking for suggestions which type of surgeries I may be able to collect the data from for my study.

I observed Nicole consenting a patient for AT&T heart failure study and made a copy of ICF for the patient to keep. I spent rest of the afternoon calling potential AT&T heart failure monitor study subjects to see if they were interested in participating. I also made some appointments for the patients to come in to sign the consent forms for AT&T study. I put the ICF forms together for Nurse walking study at HMSW where we are going next week for consenting.

November 7th

Out to School for Research on my thesis

Week of November 10th

November 10th

Daily routines were done and I spoke with the director of clinical affairs at Arizant, who makes the Bair Hugger® warming system. I told him about the study I am doing and asked him how
much of variability the Bair Hugger® warming system will produce in study results. He said that he did not know the answer and provided me with some literatures that I could review. I reviewed those literatures and forwarded the useful ones to the study staff asking for their input. I spent hours editing my daily journals.

**November 11**

I met up with Nicole at HMSW hospital at 10:00 AM to consent the nurses for Nurse Walking study. We met Leslie Rodriguez who is a PI on this study also and had him show around the hospital. Regarding my study, Leslie told me that we may not recruit the patients who require Bair Hugger® thermal blankets and if they needed it during the operations due to experiencing hypothermia, we can drop them out of the temp study. Also, we can also eliminate the use of BIS monitor on study subjects since it is a convenient diagnostic tool that is not done as a part of standard of care and has not been proven validated 100% yet. I still need to find out about the physical parameter of the forehead when measuring the temporal temperatures within the limit that gives us accurate readings. However, we may just need to revise the protocol. Les said he will talk to the other people more and get back to me. We went to ICU, and two medical surgical units to consent the nurses for Nurse Walking study. I went over the consent form with each of the subjects and answered the questions. I signed the consent form, where the study coordinator’s signature was needed. We had Les, the PI to sign the signed ICF and made copies for the subjects to keep.
November 12th

Daily routines were done and I drove to HMSW with Nicole to consent more nurses for Nurse Walking Study. We dropped off the copies of ICF from yesterday at each subject’s mail box. We went to the same units and consented more nurses who were not working the previous day. We came back to TREI office at PHD and I worked on editing the daily journal. I also filled out the expense form for traveling and adding mileages to my car for November.

Per Claire, our new nurse, I contacted the sponsor company on Crohn’s disease drug study which had been closed without any enrollment of subjects from this site and asked for the information regarding which documents to be stored and the duration of storage. The company does no longer exist so I had to call a few numbers to locate the right person to direct me. I also started to go through the old study binders on Crohn’s disease study to sort out which documents can be stored and which ones can be shredded. It was very time-consuming and tedious.

November 13th

Daily routines were done and, Nicole and I went out to HMSW again to consent more nurses for Nurse Walking study. We went to the same units from the previous days to look for any nurses who did not sign up for the study the other past two days we were there. I consented 4 nurses explaining about the study and dropped off the signed ICF at Leslie Rodriguez’s desk for him to sign as a PI.

After I came back to PHD office, I spent a couple of hours breaking down the old Crohn study regulatory binders sorting out which documents we have to keep in the storage. I found a note in the binder that this study requires of record retention for 14 years. I was surprised by the length of long duration for storage for this particular study.
I went out to Walls Regional Hospital in Cleburne by myself to pick up the supplies such as pedometers and log books for Nurse Walking study since they were now done with the study. It was a very long drive for me and took me about one and a half hours. I counted the pedometers and made sure the co-researcher at the site to sign the ICF. I went home directly from there.

November 14th
Daily routines were done and I got many emails regarding my temperature study requesting changes of my protocol and ICF. We all agreed on not enrolling the patients with Bair Hugger® warming system requirement during their surgeries. So now, I have to make amendments on inclusion/exclusion criteria on my IRB application. It needs to go through IRB review again and Skip stated that he will make a phone call to THR IRB to request an expedited approval. I spent hours revising the protocol and ICF for my study to reflect the changes and then created an amendment onto eIRB.
I and Nicole went out to HMSW again to consent rest of nurses at ICU and Med-Surge units for Nurse Walking study. We consented 3 more nurses and dropped off the signed ICF at Leslie’s office for him to sign. Leslie was in his office so we discussed about my temperature study project. I dropped off the newly revised BillNo 1 for him and the department at HMSW to sign. I told him that I have been making amendments on my protocol and eIRB application.

Week of November 17th
November 17th
Daily routines were done and I made the copies of the signed ICF for Nurse Walking study from the last week for the participants to keep. I also filed the signed ICF in the appropriate binders in
an organized manner. I made some revisions on eIRB amendment and emailed Leslie Rodriguez with updates on my study. I finished breaking down the Crohn disease study binders which had been closed and I saved some documents for record retention at a storage place. I uploaded the revised HIPPA form onto eIRB as a part of amendment requirements.

November 18th

I met up with Nicole at HMSW at 6:30 AM and Dr.Pati, the principal investigator on the Nurse Walking study, was there too. I went to Med-Surge tower 1 unit and distributed the pedometers to the nurses who signed up for the study. Also, I left the log book and remaining pedometers to the secretary with instructions. I dropped off the copies of signed ICF at their mail boxes. I and Nicole went to ICU together to drop off the supplies and the copied consent forms. We went to Leslie’s office to ask him to consent the rest of nurses that we did not catch but then he was not in the office at that time. I came back to PHD TREI office and did the daily routines. I worked on revising the protocol and ICF for my project and uploaded the newly revised documents on eIRB as a part of making an amendment. I learned that we need to upload the one version with the track changes and the other version of clean copy when we make an amendment and upload any revised documents onto eIRB. I reviewed the eIRB amendment to proofread and verify the information. I checked out previous students’ internship practicum reports to get some idea where to start in writing the thesis.
November 19th

Daily routines were done and received the email from Leslie Rodriguez that the BillNo 1 was pending from getting a signature from the department at HMSW. I started to work on writing the introduction part of thesis and created the outlines.

I went to Dr. Lipton’s office with Nicole in the afternoon to observe a subject having a visit #1.2 for Alzheimer disease study. This subject had an adverse event of skin abrasion from the study medication patch on his back. It was recorded on a case report form and Dr. Lipton wrote up the progress report. When we came back to our office, I observed Nicole entering the data into eCRF and reporting the adverse event electronically. I worked on writing the thesis until I left.

November 20th

I met up with Nicole at AMH by 7:00 AM to recruit and consent XIENCE stent data registry study subjects. Unfortunately, we could not find the appropriate potential subjects for this study today because the patients did not meet the criteria. We also went to the office of Dr. Taylor and Dr. Richardson, who are the part of the stent study team to pick up the signed consent forms. I came back to PHD TREI office and did my daily routines. My computer was running so slow I called the HELP desk to resolve the technical issues on my computer. After they fixed it, I was happy that my computer was working properly now. Leslie faxed me over the signed Bill No1 so I uploaded it with other supporting documents onto eIRB amendment. I called the THR IRB personnel to resolve the issues I had on my temp study amendment regarding the documents uploaded and they helped me through it step by step. They were very nice and helpful. I notified Les to submit the amendment as a PI. I worked on writing the thesis for less than an hour.
I and Nicole went to Dr. Lipton’s office in the afternoon to do the study procedures for a subject who was having visit #2 for Alzheimer disease study. Dr. Lipton was not in the office today so Nicole assessed the mini mental state exam while I was observing. I helped her assessing the vital signs. I also observed Nicole attempting to draw the blood from the subject but then it was unsuccessful due to hardly noticeable vein of the subject’s arm. Claire, the nurse at TREI came over and helped us to obtain the blood specimen successfully. I came back to the office and entered this subject’s data from visit one and two into eCRF including concomitant medication and medical history, and sent it to the sponsor electronically. It was a busy and productive day, I felt.

**November 21**

Daily routines were done and I emailed the study staff on my temperature study with updates. I had to call the Help desk again to resolve a technical issue on my computer and they fixed it for me. I organized the correspondence section in my study binder into a new separate binder because the study binder was getting full. Nicole gave me a short lesson of how to interpret Electro Cardio Graph, which was helpful. I dropped off the expense form for November at the tower of Texas Health Resources in Arlington on the way home.

**Week of November 24**

**November 24**

Daily routines were done and I emailed Teresa the updated journal from last week for her to sign off. I spent almost all day working on writing the thesis and reviewing the related literature.
November 25th

I met with Nicole at AMH by 8:00am to look for potential candidates for XIENCE stent data registry study. We found a lady who showed the interest so she signed the consent after Nicole went over the consent form with her. I came back to PHD office and did the daily routines. I received the email from THR IRB stating that my amendment cannot be reviewed until the amendment created by myself about a month ago has a source documents added and it is turned in by a PI. I called the staff at IRB office and discussed about the issue. I resolved the issue accordingly based on her suggestions and emailed Leslie once again to submit the amendment electronically as a PI.

November 26th

Daily routines were done and I went down to PIMIT to pick up my signed journal from Teresa’s office. I called some of Alzheimer disease study subjects’ caregivers to ask some questions about medications, the states of adverse events and medical history to record them in the case report forms. I worked on writing the thesis rest of the day.

November 27th

Out of office for Thanksgiving holiday

November 28th

Out of office for Thanksgiving holiday
**Week of December 1st**

**December 1st**

Daily routines were done and I worked on writing the thesis. I also added some more references onto my RefWorks references after literature reviewing. I edited my journal and also my thesis. I left a message on Leslie Rodriguez voice mail box to call me back to update on my temperature study.

**December 2nd**

Daily routines were done and I made some AT&T heart failure tele-management study patient charts for Claire, the nurse at TREI. Leslie spoke with Nicole about my study and he stated that he would be making some minor changes on the protocol and then let me upload it after reviewing. I reviewed and added some more information on eIRB. I emailed Dr.Gwirtz to know that I was on a waiting period on my project but I have started to write the thesis. I emailed everyone on the study team to give updates on the status of my project and to notify the time limit.

**December 3rd**

Daily routines were done and I received the revised protocol from Les this morning. I started to revise the protocol, ICF, and all the other study related documents accordingly based on Les’s suggestions incorporating his changes. I also revised the amendment on eIRB accordingly to be consistent with the newly revised protocol. I uploaded all the revised documents onto eIRB according to their requirement; one version with track changes and the other clean copy. After I was done, I emailed Les to submit it as a PI. I filed the newly revised protocol and email
correspondences into the regulatory binder for my study. Les submitted the amendment a couple of hours later and Skip, my manager stated that he was going to talk with the staff at the IRB and see if we can get an expedited review for me. Even though making an amendment seemed very time consuming and cumbersome, it was a very good learning experience for me. I made some revisions on in-service power point material for my study and printed them out to take it to HMSW.

December 4th

Daily routines were done and received an email from IRB that my amendment was in progress for expedited review. We had a holiday breakfast for professional building employees. I emailed Les to set up an appointment and we were going to meet up at HMSW at 10:30 AM tomorrow to discuss about the study and our plan. I prepared the questions to ask him and some sample study charts that I could go over along with in-service material for tomorrow. I got permission from Exergen that I can use some of their images on my thesis. I obtained useful information and related literature on Exergen temporal scanner from the web site they referred me to.

December 5th

I met up with Nicole at AMH at 7:30 AM to look for potential candidates for XIENCE stent study. After consenting one patient who showed interest at AMH, I headed to HMSW to meet up with Les. I went into his office and we discussed about the study and the plan. Les answered the questions I had about the study. I went to ICU, and 2 Med-Surge units at HMSW to pick up
the pedometers and log books for Nurse Walking Study since they were now done with the study. I left home directly from there.

**Week of December 8th**

**December 8th**

Daily routines were done and I emailed back Les with the information he requested to grant me with access to EPIC at HMSW. It will be necessary for me to access patients’ medical records for the study purpose. I returned the supplies for Nurse Walking study that I had picked up on last Friday from HMSW back to Nicole. I prepared the in-service material for my study, and cleaned out the Exergen Temporal Scanner with alcohol wipes. It also included instructions of how to use the thermometers properly and information about the scanner.

**December 9th**

Daily routines were done and I was waiting for Les to reply back to me regarding my study. I worked on writing the thesis organizing the figures. I went to Dr. Lipton’s office to pick up the sharps container which was full, and emptied it out at PIMIT. I took a new sharps container back to Dr. Lipton’s office and dropped it off. I spoke with Les in the afternoon and he said that he will call me back with the time for in-servicing later after he talks to anesthesia providers. My amendment has been approved by IRB now that I started to make some study charts with stamped ICF and HIPPA forms. I was very excited that I can finally start to recruit subjects for my study now. I prepared all the stuff needed for my study at HMSW and sent Deb Behan at HEB the approved forms for the study. I worked on making another amendment to add study staff for HEB until I left.
December 10th

Daily routines were done and Nicole received a call from a caregiver of one patient on Alzheimer study that they would like to drop out of the study due to skin irritation from the study medication patch. We prepared the equipments to take to Dr. Lipton’s for a premature disclosing procedure. I helped Nicole setting up EKG machine and observed Dr. Lipton assessing physical exams which were very interesting. I observed Nicole drawing blood for lab, assessing EKG and obtaining vitals from this patient who wanted to withdraw due to skin abrasion issue from the medication patch. We came back to our office and prepared the specimen according to the way the sponsor and the lab wanted it. Nicole shipped off the specimen and now, the patient was officially out of the study. I counted the left over study medication that was returned for accountability and recorded it in CRF. I helped Skip with filing his HIV study documents into the regulatory study binder. It was an interesting day.

December 11th

Daily routines were done and I made some more of my study charts for later use. I went to HMSW in the afternoon for my temperature study in-service at Pre-op area, Out-patient surgery center and O.R. Les took me around and introduced me to the medical staff at HMSW. I inserviced a couple of nurses at pre-operative area and Les stated that he would distribute the in-service material to the rest of them through email. I and Les discussed about the study and also practiced how to use EPIC for medical record purpose.
December 12th

Daily routines were done and I emailed Les the in-service material that he had requested yesterday with some more questions about screening process. I made a progress note template that I can refer to when writing progress notes into EPIC at HMSW. I called Les to touch base with him regarding the study.

Week of December 15th

December 15th

Daily routines were done and went to a company holiday luncheon party in Arlington. We did an ornament gift exchange game and it was fun. After I came back to PHD office, I emailed Les requesting the OR and Out patient center schedule to be faxed over ASAP for me to screen for temperature study. I also checked on the status of EPIC access by calling HELP desk and it was still pending to be completed. I let the study staff know the status of my study and left for home.

December 16th

Daily routines were done and I waited for Les to put the study together for me to start data collection as soon as possible. I called and left a message for a manager at HMSW out patient surgery center to fax over the schedule. Per Nicole, I dropped off COPD study documents at Dr. Weinstein’s office for him to sign.

December 17th

Daily routines were done and I received the schedule that were faxed over from the out patient surgery center at HMSW for today’s. However, I did not have an access to EPIC yet, which I
need to flag the subjects as research subjects into their electronic chart system. I also spoke with the manager at outpatient surgery center to fax over the next day schedules for me starting from today everyday. Finally, Les provided me with the contacts for temperature study at HMSW and the study related information. I spoke with HMSW staff regarding the study to coordinate for several hours. I received the surgery schedule at HMSW for tomorrow through the fax so I screened the ones that may be potential subjects for the study with Skip’s help. Now, I was just waiting on EPIC access issue to be resolved.

December 18th

Daily routines were done and I had to speak with Help desk to resolve an issue on EPIC system access at HMSW. I headed out to HMSW with the supplies for the study by myself. I introduced myself to everybody at outpatient surgery center and met with Mike Sadler who is a chief anesthesia provider at HMSW. Since he was in middle of a case, I had to go into the OR to speak with him and the scene inside OR was very fascinating for me. Also, I learned how to prep my self up for OR, which was interesting. Mike was telling me about how limited my study recruitment would be explaining about surgeries and equipments. I was quite disappointed but then I still went ahead and consented two patients at outpatient surgery center going over the consent forms. It was fun for me since patients were very nice and willingly signed up for the study. My EPIC was still malfunctioning and it did not let me write any progress notes into it. Also, it didn’t let me look at the records unless I break the glass (limited access due to security reasons). It was quite frustrating. I efficiently made a copy of ICF for a patient and also a copy for a medical chart for filing. I emailed Skip and spoke with Les over the phone about the updates on the study and I left.
December 19th

I went to HMSW directly from my house and due to the time conflicts, I decided to consent patients at pre-operative area today right before they went inside the OR. I introduced myself to everybody at Pre-op and I met Matt Watters who is one of CRNAs at HMSW. He helped me out with screening the surgeries and he was also telling me how limited the surgeries would be for my study. I patiently waited a patient to come back from breast screening procedure and finally spoke with patient about the study. She was willing to participate but then the consenting had to be done really quickly due to her immediate entry into OR. I thought consenting at Pre-op was not a very good way to approach the patients for the study due to the time issue. I followed the patient to the OR and the CRNA student was telling me that the patient would not have an esophageal probe placed for the procedure. That was a screen fail and I came back to Pre-op area. Les came by so we talked about making another amendment change for the better study process overall. He told me not to be frustrated since this happens frequently in research studies. Other patients I planned to ask about the study were either not a good candidate due to personal reason or cancellation of a surgery. Therefore, I went to OR to look for Mike Sadler and he helped me out with screening the surgeries for next Monday. He and I also talked about the study and upcoming amendment. I let Skip and Les know that how my day went and left.

Week of December 22nd

December 22nd

Daily routines were done and I wrote an email to Dr. Gwirtz to request a meeting time to discuss about the plan for my thesis. I organized the study equipments and supplies, and wrote progress notes on study charts. I now have EPIC icon on my PHD computer desktop but then the access
was still limited when checked. I filed the OR schedules from HMSW into a separate binder for better organization and worked on updating my journal. I started to revise the protocol and other study related documents according to how Les and I talked about. I also created an amendment to submit to eIRB and thoroughly reviewed it. I also reminded Kim at HEB to hurry and submit her record to THR system so that I can add her to the study. I sent Les an email with revised forms attached stating that the amendment was ready to be submitted after Kim submit her COI form.

December 23rd

Daily routines were done and I received an email from Kim at HEB that she has turned in her COI form on eIRB today. I double checked and confirmed to her that she was an official study member now. I also received an email from Les with the revised forms attached. I worked on revising the forms and uploaded the newly revised forms onto eIRB along with the amendment. After reviewing the amendment, I notified Les to submit the amendment. Les submitted the amendment right away and now, I just have to wait till it gets approved. I restructured previously made study charts and got rid of old ICF and inclusion/exclusion criteria forms.

December 24th

Out of office for a Holiday

December 25th

Out of office for a Holiday; Christmas day
December 26\textsuperscript{th}

Out of office for a Holiday

Week of December 29\textsuperscript{th}

December 29\textsuperscript{th}

Daily routines were done and emailed back Deb and Kim stating that I go to HEB for a site initiation visit on Friday in the afternoon. Also, I spoke with Beverly at IRB to clarify and resolve the issue occurred during the amendment application review process. I received an email saying that the amendment will be reviewed in an expedited manner. I spoke with Susan who is a security manager for medical records regarding an issue that I was not able to write any progress reports onto EPIC. She said I will not be able to write any progress notes since I am a student intern who is not a clinical provider for patients. Due to the security reason, only doctors and nurses will be allowed to write in notes into EPIC. I let Les and Skip know and Les told me to use EPIC just for medical records view only and to place the hard copy of ICF into patient’s medical chart as a mean to flag them as research subjects. My second amendment has been approved now and I contacted HMSW out patient center to fax me over the schedule for tomorrow and next Monday. After I screen the surgery schedule from HMSW, I made some study charts for HMSW and also for HEB site to start enrolling. I emailed Kim at HEB the most recently approved ICF and HIPPA forms for them to keep. I screened some more surgeries for next week until I left.
December 30th

I went to HMSW Pre operative area directly from home and looked for the potential candidates. While I was waiting on patients, I decided to go and talk to one of CRNAs to confirm the cases I chose to consent were the good ones to go into. I met Dr. Bruce Leitch who is an anesthesiologist at HMSW and explained about the study I am doing. He commented that the ones I had planned to consent would have upper body Bair Hugger® with facial drapes. He explained to me that the ones with only lower body Bair Hugger® during the operations are the ones with facial or neck surgeries, which is one of my exclusion criteria. I was disappointed to hear that and I was worried thinking about having to make another amendment. I realized how hard it could be to push forward a study sometimes. I asked a favor to Dr. Leitch to screen the next whole week’s schedule for me since other CRNAs were not present at that time. He was nice enough to screen the schedule for me even though he was very busy. He only picked one for me out of so many stating that only that one would meet the criteria for my study. I wrote an email to Skip about the situation and I decided to go talk to Les at AMH. I went into Les’s office and discussed the situation. Since we were running out of the ideas and did not want to make another amendment, we called Deb Behan at HEB. We decided to go forward the study with what we had and include even those patients with Bair hugger® on upper body as long as CRNAs do not cover the patient’s forehead region with the plastic drape during the operation for the research purpose. Les stated that he is going to write an email to Mike to ask if it will be ok for us to continue the study with the new plan. I felt little better.

December 31st

Out of office for a Holiday
January 1st
Out of office for a Holiday

January 2nd
I came to PHD office in the morning and did the daily routines. I updated my journal and worked on screening the schedule of HMSW operations for next week. I emailed Dr. Gwirtz to request a meeting to discuss about the plan for my thesis. I drove out to HEB in the afternoon to meet up with Deb Behan and Kim Barnard for a site initiation visit and I explained to them in details about how the study is supposed to be done including consenting process, screening the surgeries, study chart recording, and data collection. I also demonstrated how to use the temporal artery scanner properly for inter-rater reliability. HEB will start to collect the data as soon as they receive the temporal scanner devices from TREI and Kim will be a study coordinator over at that site. I said good bye to them and told them to contact me with any questions. I left home directly from there.

Week of January 5th
January 5th
I went to HMSW pre-op area in the morning to look for the pre-screened temperature comparison study candidates. I consented a patient according to the protocol and thoroughly explained about the research study. I made a copy of the signed ICF for a patient to keep and also one more copy for the hospital chart to be filed. I spoke with the CRNAs for this case and explained what I would be doing during the operation. I followed the patient to the OR and watched the whole operation, which was very intimidating at first but then so fascinating at the
end. It was my first time to be inside the operation room watching the operation done in a sterile manner. It was very new and interesting to me. I measured the patient’s forehead temperature every 15 minutes and also recorded the esophageal body core temperature on the data sheet for comparison. The facial component of upper body Bair Hugger® was left out for me to measure the temperatures more accurately. The surgery was done after two hours and I collected enough data from this patient. The first data collection was finally done and I could not describe how happy and relieved I was. I went back to the pre-op area and found a second patient who was just about to go into an operation. I consented her really quickly and followed her into the OR. Since I am doing the data collection part all by myself, I had to be in a hurry. Many CRNAs over here at HMSW did not know what I was doing at all so it was sort of frustrating that the study was not set up accordingly beforehand. I finished collecting the data from the second subject successfully and wrote an email with the updates to Skip, Teresa and Les. There were no more surgeries left for today so I went home feeling good that I finally have some data.

January 6th

I came back to HMSW pre-op area and consented a young lady who was about to have a surgery in the cysto room. She voluntarily agreed to participate and signed the ICF. Her surgery was delayed somehow and I had to wait about 2 hours with her in the holding area. Finally, I met a CRNA for this patient and explained to her about the study. This CRNA was delightfully willing to help and had me to follow her to the OR. Since this case was done in the cysto room, we had to wear the protective glasses and lead aprons due to high intensity radiation exposure. It was very interesting to watch what the doctor was doing on this patient and the OR scene was very eye-opening for me. This patient had to be moved to a different radiology intervention room and
I followed the staff. They moved the patient to a table with a big radiology machine and placed the patient in a prone position. Since the patient was facing downward lying on her stomach with her head in a crater, it was impossible for me to access her forehead for temperature measurements. I did have enough data pulled from this patient by that time, so I withdrew from the case thanking to the CRNA who helped me. I went back to the pre-op area break room and wrote a progress notes in the study chart. I left thinking that the work these medical staff do in the OR was so amazing and great.

January 7th

I went out to HMSW again for data collection and this patient who I was planning to consent had a commutable disease of MRSA. Therefore, I decided not to consent this patient to avoid the risk for myself. I had to wait a couple of more hours for next patient’s arrival. After long hours of waiting, I consented this nice lady who signed the ICF. I waited another hours writing a progress notes and filling out other information in the study chart until the case was about to begin. However, the SNRA on this case was telling me that this patient would not be intubated meaning that patient’s temperature would not be monitored using an esophageal temperature probe. I was so disappointed after long hours of waiting that this subject would be a screen fail. I went to the OR area to consult the CRNA for Friday schedule to make sure the patients who I was planning to consent would be intubated for sure. Dr. Leitch who was there at that time stated that the patient who I consented earlier can be intubated for the procedure so I could do my study. I was so happy and changed into the proper dress for the case right away. The surgeon showed up late so the case started late. The case was relatively short and lasted about 1.5 hours. I collected the data from the patient during the operation and then went back to the
pre-op area. All the patients were gone for today and there were no more cases left. I found one good candidate in the holding area who was about to go into the surgery in any minute but then I decided not to include him because I did not have enough time for consenting. So far, I only have 4 data collected but then I was proud of myself.

January 8th

There were no cases for me to be able to go into and collect data today at HMSW so I came to PHD TREI office in the morning today. I did the daily routines and filed the correspondence mails in the study binder. I updated my journal and made extra study charts for me to take to HMSW. I followed Nicole to Dr. Lipton’s office in the afternoon and observed her doing Alzheimer study visit with one of her patients. It is always interesting to watch a patient doing a mini mental state examination. I came back to the office and worked on making an in-service booklet for CRNAs at HMSW to spread the news about the study.

January 9th

I went to HMSW pre-op area again early in the morning and I asked a patient if she wanted to participate in the research study. It was her first time having a surgery and she stated that she felt uncomfortable. It was understandable. I found one more patient who met the criteria and explained about the study. He signed the consent form and I asked Nancy, one of the CRNAs at HMSW to do data collection on this patient for me. Meanwhile, I went to the Out patient surgery pre-assessment center to consent one patient who is going to have a surgery next Monday. However, the patient was already gone. So, I went to the OR and obtained the OR
schedule for next week. I pre-screened them to see which cases I should go after. I went to school in the afternoon to meet up with Dr. Gwirtz to discuss about the plan for my thesis.

**Week of January 12th**

**January 12th**

I went to HMSW pre-op area early in the morning but the potential subjects for temp study already went into the OR. The other case was canceled. After a couple of hours of waiting, I consented one patient and followed her into the OR with Dr. Jordan, the anesthesiologist on this case. I measured the temporal temperatures every 15 minutes for the first hour in the OR, which I got to watch the fascinating operation and then, Nancy, one of CRNAs at HMSW came in and took over. I waited more hours trying to consent the other patient who was added to the schedule last minute. The patients did not want to participate in the study because he did not want to have an extra person to be in the OR for his case. I obtained the updated schedule for tomorrow from the OR and pre-screened the schedule one more time. I went to the outpatient surgery center to consent one patient but then the nurse recommended me not to since the patient was running late for his appointment. I worked on writing the progress reports and filling out the other study related paper works in the study binder and left for home.

**January 13th**

I started my day at 9:00 AM today at HMSW because the first patient I was planning to consent was having a surgery at 11:00 AM. The patient agreed to take a part in the study and signed the consent form. I had Nancy, one of the CRNAs to collect the data for me on this one case and went to the out patient surgery center to look for some other candidates. I found a lady who can
be a good candidate and explained her about the study in detail. However, she did not want to participate for some reason and I learned how each individual reacts differently on a same subject in patient care and research from this experience. I spent the rest of day screening for the potential subjects going over the OR scheduled for this week.

**January 14th**

The early morning case I was going to go in was canceled so I waited a couple more hours for the other candidate to show up at the pre op area. I consented this patient and had Nancy to collect the data for me. The other patient who I was planning to consent had MRSA, a commutable disease so I decided not to ask this patient. I found another patient and did the data collection myself. The patient was morbidly obese so I was curious if Exergen device really does work well on obese patients too just like how the manufacturers claimed. After I was done with data collection, I came back to the pre-op area to look for some other patients. The patient was sleeping so I did not want to disturb. I obtained the data worth of 2 patients today so I left for home feeling accomplished.

**January 15th**

I started my day little late today because the first case was scheduled to be at 1:00 PM. I went to the pre op area at 10:30 AM and consented this nice gentleman who was willing to participate gratefully. There was another case who was a good candidate but then I could not go in due to the time conflict. I asked other nurses if I can borrow their thermometers but then they only have limited numbers of thermometers for themselves. Also, Les told me not to use theirs for calibration issues. I asked Matt, one of CRNAs to collect the data for me. He accidentally
collected the temperature every 10 minutes instead of 15 minutes, which was a protocol deviation. Therefore, the data collected by Matt was useless and had to be thrown away. I was disappointed but then I was kind of glad that more CRNAs started to recognize the research study I was doing.

**January 16th**

I started my day again at HMSW and consented this lady at the holding area. I answered her questions and waited for her case to begin. However, the CRNA on this case told me that the patient will be placed in prone position and it will be hard for me to get to the area being measured. Also, the case will be done in 30 to 40 minutes since the surgeon is really quick. I unfortunately had to exclude the patient and recorded her as another screen fail. I drove to PHD for a meeting with Teresa, Skip and Les. I came to the office and did some backed up work such as filing the correspondence emails, updating the journal, and organize the OR schedule book, etc. During the meeting, we talked about the plan and updates on my study, which was very helpful. I let them know what the issues have been during the data collection. I was told to start to enter the data into the Excel, instead of waiting till the last minute. I will work on that starting from the next week.

**Week of January 19th**

**January 19th**

I went to HMSW pre-op area at 5:30 AM early in the morning and approached a good candidate. She seemed uncomfortable at first but after my full explanation about the study, she voluntarily decided to participate in the study. She was having a right shoulder rotator cuff
repair and I soon realized that this type of procedure is not a good case for my study due to the way of draping the patient. I still tried my best to collect the temperatures throughout the operation even though it was very hard to reach the forehead through the layers of drapes. I came back to the pre op area and consented another patient. Matt, one of CRNAs at HMSW stated that the OR I was trying to go into for data collection was very small and it will be very crowded. Therefore, he told me that he could do the data collection for me so I went to the outpatient center to consent a patient who is going to have a surgery tomorrow. There were no more cases which met the criteria for the study so I obtained the OR schedule for tomorrow and went to Texas Health Resources Arlington tower to pick the additional thermometers, which were dropped by Skip, my manager. Upon Les’ request, I went to HEB to drop off two of the complimentary thermometers by Exergen. It seemed like a long day for me.

January 20th

Now that I have 3 Exergen thermometers provided for me for the study, I went to HMSW feeling more prepared. I arrived there by 7:00 AM and consented one patient who showed interest in participating. Data was collected on this patient by Matt, CRNA and I collected temperatures on another patient who had been already consented for the study yesterday. I collected the data on this patient throughout the operation and it was very exciting to watch the operation. I had a rare opportunity to get to see the enormous size of fibroid, which the doctor said it is very rare. I went to the Out patient center and consented one more patient before I left.
January 21st

I arrived at HMSW pre op area at 6:00 AM in the morning and consented two patients who were having the surgeries at the same time quickly. I went to the OR break room and politely asked the CRNA on one of the cases to do the data collection for me. I explained clearly how to use the thermometer properly and also how to collect and fill out the data sheet. I worked on organizing the data and also wrote up the progress notes accordingly. In the afternoon, I collected one more subject’s data and I obtained 3 subjects worth of data today. I emailed the study staff with the updates. It was a very productive day and I was happy that I took an advantage of having multiple thermometers for the study today.

January 22nd

I started my day late today because the first case starts at 10:30 AM today. Unfortunately, the patient I had consented already at the out patient surgery center screen-failed by having a Laryngeal Mask Airway (LMA) instead of having an esophageal temp probe placed in her esophagus. I asked the anesthesiologist on this case if the patient can be intubated for the research purpose but he said no. So, I recorded her as another screen fail. The other patient who I was planning to consent rescheduled his surgery so I waited couple more hours. Meanwhile, I pre-screened next week’s OR schedule and had one of the CRNA to help me with questions about some procedures. I was going to consent this one in-patient who met the criteria but he went to the holding room right away without checking into the pre-op area. He was getting prepared for the surgery and there was no time for me to interrupt. Today, I did not have any single data collected other than screen fails so I was very disappointed.
**January 23rd**

I showed up at the pre-op area at 6:00 AM today and the day surgery pre-op area moved to the newly remodeled place. Therefore, it was very hectic and the nurses were very busy. I waited until the nurse prepped the patient for his surgery and went into his room. I consented one patient in a private room setting and he agreed to participate. The other patient who was supposed to have a surgery at the same time but in the different rooms canceled her surgery so I could not consent her. I went into the OR and collected the temperatures. Due to the upper body Bair Hugger® blowing warm air, it seemed like the temporal temperature measurements were way off from the core esophageal temperatures. I collected data for up to 2 hours and then came out of the OR. Another patient who I was planning to consent was having a LMA and the procedure was less than an hour according to Dr. Jordan, the anesthesiologist. I learned to avoid the procedures such as lithotripsy or hysteroscopy, which require patients to have LMAs during the procedures. I checked the updated schedule of today and there was no more case for me to go into due to the type of anesthesia and age issues. So I left home early for today and worked on updating my journal.

**Week of January 26th**

**January 26th**

I showed up the pre-op area at 6:00 AM in the morning and waited the nurse to finish preparation on a patient who I was planning to consent. The patient signed up for the study but the CRNA on this case had an objection intubating the endotracheal tube inside. The CRNA stated that the patient needed a LMA so unfortunately, it was another screen fail. I waited a couple hours for the next patient. I obtained her consent in a private room setting. However, due to her medical
condition of diabetes, she was also required to have a LMA to prevent gastric reflux. I was so disappointed and felt unproductive. Another patient I was waiting ended up canceling his surgery. So far, I have had 6 screen fails and 3 rejections due to several reasons. I went home hoping for tomorrow to be a better day.

**January 27th**

Due to the severe weather of today, I could not make it to HMSW. Instead, I stayed home and worked on updating my journal and entering all the data I had collected so far into a spreadsheet. So far, I only had 17 subjects worth of data but then data entry was somewhat time-consuming. However, it was a good experience for me. I let my manager know that I was working at home today and he said that was fine.

**January 28th**

Out of office due to the freezing weather

**January 29th**

I showed up at HMSW at 9:00 AM and obtained the updated OR schedule for today. I pre-screened the schedule and then went to go see Dr. Bruce Leitch, the anesthesiologist for a couple questions about some procedures. I had to wait about couple hours and then went to the pre-op area to go see if the patient will have a LMA and not intubated. One person I was planning to consent was going to have a LMA so I did not even bother to consent him. So that it will not be another screen fail. The other person I went to ask agreed to participate in the study. I made a
copy of the signed consent for the patient and also placed one in the hospital chart. Data was collected during the procedure by me and I left afterward.

January 30th
I arrived at HMSW 8:00 AM in the morning and approached the candidates in the pre-op area. One was getting a LMA so I had to withdraw from enrolling him into the study. The other one agreed to participate in the study so I collected data myself during the procedure. When I came out to consent another patient, he was already drugged up and falling asleep. I could not get him to consent since he was falling asleep. I waited for another candidate to arrive and I pre-screened next week’s OR schedule meanwhile. While I was collecting data on a patient inside of OR, Mile Sadler and I discussed about the limitation of my study, which was very helpful. There was another case added which was supposed to start at 3:30 PM, so I waited until the patient arrived at the pre-op area. I obtained her consent but then the case was delayed. So, the case started at 4:30 PM and I collected data till 6:30 PM. In total, I enrolled 3 more subjects into the study today and it was a very tiring but rewarding day.

Week of February 2nd
February 2nd
I started my day at 6:00 AM in the morning today at HMSW and data collection was done on one patient who agreed to participate in the study. One another patient who was having a surgery at the same time ended up having a LMA so she was not a good candidate for the study. I went to the Out patient center to look for some other candidates for the study and I obtained the consent from this lady who was having a surgery on this coming Thursday. I drove to PHD and
did some backed up administrative work such as correspondence filing in the binder, making more study charts, and organizing the OR schedules, ect. I wrote an update email to all the study staff regarding the study status and left the office. I stopped by at the Arlington Texas health resources tower to drop off the expense form for January.

February 3rd
Data was collected on two patients today who signed the ICF. During the data collection period, I discussed my study with Keith Greene, one of the CRNAs who helped me with a lot of helpful information. First case I went into ended really fast because the surgeon was very fast. So, I collected only 3 measurements but I decided to assign her with a study subject number. I received an esophageal temperature probe as a souvenir from Keith. It was a fun day for me.

February 4th
I arrive at HMSW at 6:30AM and consented 2 patients really quick who were about to go into the OR. One ended up having a LMA so it was another screen fail for me. The data was collected by Vickie, CRNA on the other patient during the procedure. Meanwhile, I worked on filling out the demographic form, inclusion/exclusion criteria and progress notes. I consented one more patient at 8:00 AM who was very willing to participate and collected the data myself during the procedure. Last patient I was planning to consent already went into the OR when I came out from the previous case. I found out that some surgeons are really fast so the cases start earlier than anticipated sometimes. I went home in the afternoon and worked on entering all the data collected so far into the spreadsheet. I also worked on updating my journal.
February 5th

I started my day little late today at 9:00 AM today because the first patient was already consented a few days ago at the out patient center. I collected the data during the procedure. Right after the procedure, I obtained consent of another patient and I followed the patient to the OR. I collected the data myself. Data was collected on a total of two subjects today.

February 6th

It was the last day of data collection for me at HMSW and I arrived at HMSW at 6:00 AM. Consent was obtained from two patients who were going into the OR at the same time so Sandy, one of the CRNAs volunteered to collect data for me on one patient. I prepared myself for the OR and went inside to collect the data. However, the circulator on this case told me the bad news that I would not be able to measure the patient’s forehead temperatures at all. Even though she met all the criteria for the temperature study, the way they draped her for the robotic procedure would not allow me to access her forehead at all. Basically, her whole body was going to be covered with the sterile drapes and the robot was going to access her from the head. It was another screen fail. I was disappointed but it was something new I learned. I waited an hour and consented this girl. I collected her data for one hour and 45 minutes during the procedure and I thanked to everyone for helping me out with the study when I was leaving. I stopped by at the pre-op area and also the out patient area to say thank you and bye. Data was collected on 2 patients today and a total of 30 patients completed the study while I was interning at TREI. Even thought I did not succeed in collecting all 50 patients’ data for the study due to the time limitation, it was truly very valuable experience for me over all. I really appreciate the opportunity given for me from TREI that I was be able to experience many aspects of clinical
research even including troublesome and tedious part of it also. I know definitely that this
experience will help me in many ways in my future.
APPENDIX

Appendix A. Permission to use images email Letter from Exergen

From: Marybeth Pompei [mpompei@exergen.com]  
Sent: Tuesday, September 09, 2008 7:35 PM  
To: Lee, Su  
Subject: RE: TAT-5000 EXERGEN Temporal Scanner

Attachments: Specifications TAT-5000 REV 3.pdf

Su, I’ve attached a listing of the regulatory certifications we have received on the TAT-5000, which includes the Class II designation.

The THR pricing I can provide to you as a member of Texas Health Resources, which I did, but it would not be appropriate for me to provide the letter of agreement with THR. However, you could confirm this with Mr. Don Black, Corporate Supply Chain Management for THR Corporate.

We would be pleased to provide approval for you to use any of the graphics. If you would let me know which graphic(s) are of interest, we can give you high resolution images.

Marybeth Pompei, Senior Vice President  
Chief Clinical Scientist  
Exergen Corporation  
400 Pleasant Street  
Watertown, MA  02472  
617-923-9900 x 6202  
mpompei@exergen.com  
www.exergen.com

From: Lee, Su [mailto:SuLee@texashealth.org]  
Sent: Monday, September 08, 2008 10:15 AM  
To: Marybeth Pompei  
Subject: RE: TAT-5000 EXERGEN Temporal Scanner

Hi Marybeth

This is Su Lee and I was wondering if you can provide with us some documents that can prove it’s price and what classification it is. Because I will have to submit those documents with IRB in order for us to start the study to prove that temporal temperature scanner provides accurate readings compared to core temperature. Also, I was wondering if I can possibly use a diagram that was in your manual, which we found on a website. I will need to have your approval to use any source from Exergen on the publication.

Thank you for your prompt reply and help.

Respectfully,  
Su Lee
Appendix B. Inclusion/Exclusion criteria for the study

**Temporal Thermometry Study**

### Inclusion Criteria

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<tr>
<td>1.</td>
<td>Adult participants who can speak and understand English</td>
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<td>2.</td>
<td>Adult participants who can read and understand an English consent form</td>
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<tr>
<td>3.</td>
<td>Adult participants admitted to the operation room with an esophageal thermometer at HMSW or HMHEB</td>
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<td>4.</td>
<td>Participants older than 18 years old but less than 65 years old</td>
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<td>5.</td>
<td>Participants without any diseases that will interfere with measuring core temperatures using an esophageal thermometer</td>
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<td>6.</td>
<td>Participants willing to allow medical staff to perform forehead temperature along with esophageal temperature monitoring during the study</td>
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### Exclusion Criteria

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<tr>
<td>1.</td>
<td>Adult participants with skin rash on forehead or any diseases that will interfere with temperature monitoring by esophageal thermometers.</td>
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<td>2.</td>
<td>Participants undergoing facial, neck, neurological or ear procedures to avoid touching sterile fields by measuring temporal temperatures</td>
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<td>3.</td>
<td>Adult participants who have warming devices over the area being measured using a temporal artery thermometer anytime during the procedures</td>
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<td>4.</td>
<td>Participants whose core temperatures will not be monitored during the procedures, such as patients who have a Laryngeal Mask Airway (LMA) and their nasal or axillaries temperatures monitored instead.</td>
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<tr>
<td>5.</td>
<td>Any participant that the principal investigator considers not appropriate for this study</td>
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Does patient meet criteria?  Yes/ No

---

Study Coordinator signature  
Date
Appendix C. Informed Consent Form to be in the study
ADULT CONSENT FORM TO BE IN RESEARCH

Section                                                                                      Page
A. Who is conducting this research study? ................................................................. 2
B. What is the purpose of this research study? ........................................................... 2
C. Why are you invited to take part in this study? ...................................................... 3
D. How many people will take part in the study? .......................................................... 3
E. What will you be asked to do? ..................................................................................... 3
F. Can you stop being in this study? ............................................................................... 4
G. What are the possible risks, side effects, or discomforts of being in this study? .... 4
H. What are the benefits of taking part in this research study? ................................. 5
I. What options are there to being in this study. ............................................................ 5
J. Are there potential conflicts of interest? ................................................................. 5
K. What about your privacy? What about confidentiality of your private health information? 5
L. What are the costs of your being in this research study? ........................................ 5
M. Will you be paid for being in this study? ................................................................. 6
N. What if you have an illness or injury related to being in this study? ....................... 6
O. What are your rights as a human research participant? ........................................... 4
P. Whom do you call if you have questions or problems? .......................................... 6
Q. Consenting to be in this study: .................................................................................. 7

You are being asked to take part in a research study. This form describes the study. Please read it carefully and discuss it with the research coordinator BEFORE you agree to take part by signing the form.

TEXAS HEALTH RESOURCES and
UNIVERSITY OF NORTH TEXAS HEALTH SCIENCE CENTER (UNTHSC, FORT WORTH, TX)
TEMPORAL TEMPERATURE COMPARISON STUDY

A. Who is conducting this research study?

Principal Investigator:  
Les Rodriguez MSN, MPH, RN, CPAN  
Clinical Education Specialist  
Harris Methodist Southwest (HMSW)  

Phone: 817-433-6251  
Mobile: 817-327-0509

Co-Investigators:

Deborah Behan PhD(c), RN-BC  
Nurse Researcher/Clinical Educator  
HM H-E-B  

Phone: 817-685-2070  
Mobile: 940-367-4758

Patricia A. Gwirtz, Ph.D., F.A.C.C.  
Professor  
Department of Integrative Physiology  
University of North Texas Health Science Center at Fort Worth

Sub Investigators:

Su Lee  
Research Student, TREI  

Phone: 214-345-4121  
Mobile: N/A

Other Study Staff:

Nicole Richter  
Study Coordinator, TREI  

Phone: 214-345-8339  
Mobile: N/A

Study Site:  
Harris Methodist Southwest Hospital (HMSW) and Harris Methodist HEB Hospital (HMHEB)

This research study is sponsored by The Research and Education Institute for Texas Health Resources and the University of North Texas Health Science Center in Fort Worth. The study sponsors provided money to cover costs related to the conduct of this research study.

B. What is the purpose of this research study?

The purpose of this study is to compare two different types of adult temperature devices. One is the forehead monitor. The other will be a core esophageal thermometer that tells us the temperature inside your body. We are trying to see if both measurements are close to each other (eg. one is 37.2 and the other is 37.5). We would like there to be a less than 1 degrees difference in Celsius.

The forehead thermometer that will be used is the: TemporalScanner by Exergen, which is a hand held unit.  
The core esophageal thermometer that will be used is the: Vital Temp esophageal temperature probe by
Vital Signs. This probe will be placed in the patients’ esophagus by an anesthesia provider as a standard of care in many, but not all, patients. Patients having certain types of procedures (e.g. Colorectal) will have an esophageal core temperature probe placed as a standard of care by anesthesia providers. It is common for anesthetized surgical patients to experience decreased temperatures so the warming devices such as warm blankets or warm air conducting systems are used to keep patients warm frequently during the procedures. If patients need some sort of warming devices during the procedures, patients who will only have lower body warming will be included into the study.

Little is known about the accuracy of forehead temperatures compared with core temperatures in adults. Many studies have shown accuracy in infants and children. Few studies have been done in adults. We hope this study will allow us to decide if the forehead temperature monitor is as accurate as the core temperature measurement. In doing so, healthcare workers can be confident in the temperature measurements they take with a forehead monitor.

C. **Why are you invited to take part in this study?**

You are being asked to take part in this study because you are a patient in this hospital requiring regular temperature measurements for your care. We hope your participation will help us decide whether forehead temperature readings are close to the core esophageal temperature readings. In the future, this study may help other medical staff feel confident when using the forehead temperature monitor.

Research studies include only people who choose to take part. Please take your time to make your decision and discuss it with your friends, family and/or doctor. **Remember that your decision to be in this study is your choice.**

D. **How many people will take part in the study?**

In total, about 100 people will take part in this study at two different hospitals meaning 50 subjects at each site. Only patients who are admitted to the operating room (O.R.) at HMSC or HMHEB with esophageal temperature probe placed by an anesthesia provider to measure the core temperature will be included.

E. **What will you be asked to do?**

You will be asked to read and sign an informed consent form. You may ask questions to help you decide. Once you voluntarily agree to take part in this study, you will sign the consent form and a copy will be given to you.

The study staff will take your temperature every 15 minutes while you are in the O.R. We will measure your temperature in two different ways. One way will be with a forehead monitor. The other way will be done using a core esophageal temperature probe (a probe that sits inside the tube you swallow with) which is placed by an anesthesia provider to measure the core temperature.

**Procedures**

The following research procedures will be done during this study:
Upon entering the HMSW or HMHEB Operating Room:

1. Your core esophageal temperature will be measured using an esophageal thermometer probe every 15 minutes, which will be placed by an anesthesia provider as a standard of care, while you are in the O.R. The research study coordinator will read the core temperatures off the monitors that an anesthesia provider uses to monitor you throughout the operations.
2. Your forehead temperature will be measured using a hand-held unit, every 15 minutes while you are in the OR by the research coordinators.
3. The research coordinator will record these temperatures on a log sheet.
4. After your temperature readings are recorded, the study will be completed.

The procedures in this research study may be standard. "Standard Procedures" would be done even if you did not take part in this study.

F. Can you stop being in this study?

Taking part in this study is up to you. You may refuse to be in the study or you may stop being in this study at any time. If you decide not to participate, or you withdraw, you will not have any penalty or loss of benefits to which you are entitled and this will not affect your future medical care. The investigators may decide to take you off this research study, even if you would like to continue. Some examples of why the investigators might take you off the study are:

- If the investigators determine that it is in your best medical interest;
- If your condition worsens;
- If you fail to follow study directions;
- If it is discovered that you do not meet the study requirements, at the principal investigator's discretion;
- If the whole study is stopped or modified for any reason;
- For administrative reasons, such as the target number of subjects has already entered the study.

Will the researchers tell you about new information that may affect your decision to continue in this study?

The researchers will tell you if they learn important new information that may affect your health, welfare, or your willingness to stay in this study. If new information is given to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

G. What are the possible risks, side effects, or discomforts of being in this study?

There are no risks expected when we take your temperature using a forehead scanner. However, measuring core body temperature using an esophageal temperature probe may be considered invasive but is done routinely in the hospital setting. Core temperature will only be collected if it is part of your routine care needed for your procedure. Standard care will not be affected by this study. Standard care risks for placement of an esophageal temperature probe, which is not a part of study, may include possible infection or sore throat.
H. **What are the benefits of taking part in this research study?**

There are no benefits to participating in the study. Subjects will not be paid during this study.

However, in the future, it will allow healthcare providers to confidently take your body temperature with a forehead monitor, which are quick and easy to use.

We hope the information learned from this research study will benefit other patients in the future by helping us to learn which method of measuring the temperature is most accurate.

I. **What options are there to being in this study**

You do not have to take part in this research study. You will continue to receive standard of care for temperature monitoring.

J. **Are there potential conflicts of interest?**

The principal investigators and the study staff do not have any financial interest in the study results. This means that they will not make or lose money due to the results of the study (positive or negative). HSMW Hospital and HMHEB Hospital do not have financial interests in the study results, either.

K. **What about your privacy? What about confidentiality of your private health information?**

In research, information collected about you will be compared to information collected about other research study participants. Most research study records have some sort of information that may identify you. However, all research data will be de-identified so it cannot be traced back to you. The database will be password-protected and only staff on the study team can enter the database.

Your initials will be recorded, along with date of birth, ethnicity, reason for admission to the hospital, and body temperature readings.

You will be asked to sign a separate “Authorization to Use and Disclose Protected Health Information” form. This form will outline with whom your information may be shared with. It will also state under what circumstances it may be shared. You can choose not to give us permission to use this information. This choice is a very important right that you have. If you do not give us the permission to use this information for the research study, you will not be able to take part in this study. See section O for more information about your rights as a research participant.

**How will information about you be used in teaching and publication?**

If information about the research study is used for teaching or in publications, private information will not be made public and your identity will be kept confidential.

I. **What are the costs of your being in this research study?**

You and your insurance company will not be charged for your participation in this research study.
M. **Will you be paid for being in this study?**

You will not be paid for taking part in this study.

N. **What if you have an illness or injury related to being in this study?**

Every effort will be made to prevent injury to you as a result of being in this study. If you have a study-related injury, tell your researcher right away. Your health insurance company may not cover you for an injury that is due to being in this study and is not due to your condition. Neither your researcher, Texas Health Resources, or the hospital, agree to give free medical or hospital care or payment for any injury from being in the study. By signing this consent, you do not give up any legal rights that you already have.

In case of research-related injury, please call the study staff or the principal investigators and notify them at the phone numbers listed in Section A.

O. **What are your rights as a human research participant?**

- You have the right to refuse to take part in a research study without any penalty or loss of benefits to which you are otherwise entitled. **Taking part in this research is your choice.**
- You have the right to drop out of this study at any time without any penalty or loss of benefits to which you are otherwise entitled.
- You have the right to be given important new information that may affect your health, welfare, or willingness to stay in this research.
- You have the right to ask questions at any time and have them answered as soon as possible.

Whether or not you take part in this research study or decide to leave the study, will not affect the care you receive by your doctors or the hospital.

P. **Whom do you call if you have questions or problems?**

If you have questions or concerns about this study, please contact the principal investigators or one of the study staff listed in Section A of this consent form.

If you have questions, concerns, or comments about your rights as a research participant, please contact the one of the parties listed below:

- Institutional Review Board (IRB)
- Texas Health Resources
- Phone: (817) 462-6746
- Email: irb@texashealth.org

- Institutional Review Board (IRB)
- University of Texas Health Science Center at Fort Worth, Texas
- Phone: (817) 733-0409
- Email: bgladue@hsc.unt.edu

The IRB includes doctors, scientists, non-scientists, and community members. The IRB reviews,
IRB No: Pro478
Approval Date: «ApproveDate»  Expiration Date: «ExpireDate»
approves, and monitors all human research at Texas Health Resources. The IRB’s role is to review research studies in order to protect the rights and welfare of subjects taking part in research.

Q. **Consenting to be in this study:**

You are deciding if you want to be in this study. You should not sign until you understand all the information in this form and until all of your questions about this study have been answered. Signing this form shows that you have decided to be in this study, having read (or been read) the information given above. Signing this form also shows that you give permission for your private health information from this study to be shared.

1. I understand this is a research study. [ ] Yes [ ] No
2. I understand risks of being in this study. [ ] Yes [ ] No
3. I understand how long I will be in this study. [ ] Yes [ ] No
4. I understand the purpose and hopes for outcomes of this study. [ ] Yes [ ] No
5. I understand I can stop being in this study at any time. [ ] Yes [ ] No
6. I understand that I have a choice whether or not to be in this study. [ ] Yes [ ] No

If you did not answer “yes” to all of the above questions, please review being in this study again with the researcher. You should only sign this form on the signature page at the end of this form when you have answered “yes” to all of the questions above.

You will be given a copy of this signed and dated consent form.

**SIGNATURE BY THE SUBJECT OR THE SUBJECT'S LEGAL REPRESENTATIVE:**

Name of Subject (Print) Signature of Subject Date of Signature

If subject is unable to sign the form, please state the reason below:

Name of Legal Representative (Print) Relationship to the Subject

Signature of Legal Representative Date of Signature

Statement of study staff and main researchers obtaining consent:

Page 7 of 8
I have fully explained this study to the subject. I have discussed the study’s purpose, its experimental and non-experimental procedures and interventions, the possible risks and benefits, the standard and research aspects of the study, the alternatives to participation, the voluntary nature of the participation, and the source of funding for the research and conflict of interest on the part of the research staff. I have also discussed the information required under the HIPAA Privacy Rule. I have invited the subject to ask questions and have answered any questions that the subject has asked.

Signature of the principal Investigators/Study staff  Date of Signature

Printed name
Appendix D. HIPPA form
AUTHORIZATION TO USE or DISCLOSE
PROTECTED HEALTH INFORMATION FOR RESEARCH

Signing this form gives authorization (permission) for the researcher, health care facility and IRB to use and disclose (share) your protected (private) health information for the research named here:

Title of Research Project: A comparison of two modalities of temperature measurement; Temporal versus Esophageal throughout the intraoperative period.

Leader of Research Team: Leslie Rodriguez MSN, MPH, RN, CPAN
Deborah Behan PhD(c), RN-BC
Patricia Gwirtz Ph.D., F.A.C.C.

Study Staff: Nicole Richter
Su Lee

Address: Harris Methodist Southwest Hospital
Department of Education, 6100 Harris Parkway.
Fort Worth, Texas 76132

Harris Methodist HEB Hospital
1600 Hospital Parkway
Bedford, Texas 76022

Phone Number: 817-433-6251 ext 6251 / 817-685-4136 / 214-345-4121

What information will be used or shared?
If you give authorization, the health care facility where you received treatment or testing will make available (disclose) to the researcher your protected health information as necessary for this study as described below. The specified information to be released may include, but is not limited to: history, diagnoses, and/or treatment of drug or alcohol abuse, mental illness, or communicable disease, including Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS).

Why will the information be used or shared?
If you give authorization, the researchers may use or disclose your protected health information for the following specific purposes:

1. To organize the study accordingly

Revised 02/21/2003
Research Authorization for Protected Health Information
Research Privacy Form 1
2. To discuss the study among the study team members.

The researchers may also use or share your private information to develop new procedures or commercial products.

Who will get my information?
If you give authorization, the researchers may disclose your protected health information to the research sponsor, the Institutional Review Board (IRB) overseeing the research.

Confidentiality
The researchers may report their findings in scientific reports, but they will not name you in their reports. The researchers will try to keep your information confidential, but this cannot be guaranteed. The government does not require everyone who might see or receive your information to keep it confidential, so it might not remain private.

Voluntary Choice
The choice to give authorization to use or disclose your protected health information is voluntary. It is completely up to you. No one can force you to give authorization. Refusing to give your authorization will not affect your ability to get normal treatment, payment, or health benefits from your physician or health care provider. However, you must give authorization for the researchers to use or disclose your protected health information if you want to participate in the research.

Canceling Permission
If you give the THR researchers authorization to use or disclose your protected health information, you have a right to cancel your authorization whenever you want. However, canceling your authorization will not apply to information that the researchers have already used or disclosed.

To cancel your authorization (permission), you must write to either of the following:

1. The Leader of the Research Team named at the beginning of this form or
2. Director Research Compliance
   Texas Health Resources, 612 E. Lamar Blvd. Suite 1200, Arlington Texas 76011
   If you have questions call: 817-462-6746

End of Permission
Unless you cancel it, authorization to use or disclose your protected health information for the research will end when the publication becomes available.

Giving Permission
By signing this form, you are giving Texas Health Resources (THR), and the research team named on this form, authorization (permission) to use or disclose (share) your protected (private) health information for the research named on this form.
Patient/Subject Name: ____________________________ Date of Birth

Signature of Patient-Subject or Legal Representative** Date

** If signed by a Legal Representative, a description of the relationship to the Patient-Subject and the Authority to Act as Legal Representative must be attached to this form. A signed copy of this form must be given to the Patient-Subject or the Legal Representative.
Appendix E. Patient Demographics

TEMPORAL TEMPERATURE STUDY
Demographics Form

Study #: ____________________________

Subject Name (Last, First) : ____________,________________

Subject Initials: _____________________

Gender of Subject: M/ F

Ethnicity :____________________

Age of Subject: ________years old

Date Consented: _______/_______/_______________

Reason for Operation: ________________________________

Type of Operation: ________________________________

Date of Service: ________________

Bair Hugger Used (YES; UPPER OR LOWER BODY, OR NO)
Subject Initial: __________   Study Number: ___________

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<th>Date/ Time</th>
<th>&lt;Progress Report&gt;</th>
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## TEMPORAL TEMPERATURE STUDY

**P.I.: Les Rodriguez**

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<th>Subject initial:</th>
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**Location:** OR at Harris Methodist Southwest In Fort Worth, Texas

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<th>Time</th>
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Name of person filling out form: ____________________________

Signature of person filling out form: ____________________________
REFERENCES


