PROTOCOL TITLE:

Anapod™ Humi-Therm Heated Humidification System Breathing Circuit versus Bair Hugger™ Warming Blanket for Intraoperative Maintenance of Body Temperature in Pediatric Patients Undergoing Dental Procedures: a Prospective Randomized Non-Inferiority Study

PRINCIPAL INVESTIGATOR

Benjamin Kloesel MD
Department of Anesthesiology
Assistant Professor
612-301-1245
bkloesel1@umn.edu

Co-Investigator 1

Kumar Belani MD
Department of Anesthesiology
Professor
612-624-9996
belan001@umn.edu

Co-Investigator 2

Soraya Beiraghi, DDS, MSD, MS
Department of Developmental and Surgical Sciences
Professor
612-624-5997
Beira001@umn.edu

Support Personnel

Melissa Cohen
Jason Hall
Ryan Eskuri DO

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	6/27/19	See stipulation letter	YES
2	4/28/2020	Updated contact information, length of enrollment period, and also see stipulation letter for more	YES

Table of Contents

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ABBREVIATIONS/DEFINITIONS

Include any abbreviations or definitions for key or technical terms you use in your protocol.

- MRN = Medical Record Number
- IV = Intravenous
- PACU = Post Anesthesia Care Unit (Recovery Room)

STUDY SUMMARY

Study Title	Anapod™ Humi-Therm Heated Humidification System Breathing Circuit versus Bair Hugger™ Warming Blanket for Intraoperative Maintenance of Body Temperature in Pediatric Patients Undergoing Dental Procedures: a Prospective Randomized Non-Inferiority Study
Study Design	Prospective randomized non-inferiority study
Primary Objective	Determine non-inferiority of Anapod™ Humi-Therm Heated Humidification System Breathing Circuit compared to Bair Hugger™ Warming Blanket
Secondary Objective(s)	Need for hyperthermic or hypothermic rescue intervention Correlation of 3M SpotOn Temperature Monitoring with rectal temperatures
Research Intervention(s)/ Investigational Agents	Anapod™ Humi-Therm Heated Humidification System Breathing Circuit and BairHugger ™ Warming System
IND/IDE # (if applicable)	N/A
Investigational Drug Services # (if applicable)	N/A
Study Population	Pediatric patients undergoing dental procedures
Sample Size (number of participants)	256 (128 patients per study arm)
Study Duration for Individual Participants	Duration of one dental procedure (1-6 hours) including recovery period in the postoperative care unit until discharge home or admission to the floor.

1.0 Objectives

Purpose: Temperature management is an important aspect of perioperative care that falls under the purview of the anesthesiologist. Temperature is recognized as one of four primary vital signs and significant deviations from normal values may result in patient harm. General anesthesia disrupts the body's temperature homeostasis by inhibiting temperature regulation mechanisms such as vasoconstriction/-dilation, shivering and behavioral interventions (donning clothes or leaving an area with excessive heat, for example). Anesthetized patient have a tendency to become hypothermic, especially during long surgical procedures. This results from both the redistribution of cooler peripheral temperatures into the cord (due to vasodilation) as well as actual temperature loss to a cold operating room environment (which is maintained at a lower temperature for the comfort of fully gowned surgeons and nurses). In addition, large surgical incisions predispose the patient to hypothermia through evaporation and convection.

Hypothermia is a recognized risk factor that predisposes the patient to an increased metabolic rate, increased oxygen demand, coagulopathies, impaired wound healing, impaired immune function and increased risk of infection. Therefore, maintenance of normal body temperature is an important goal of every general anesthetic - and is a well-accepted quality metric associated with patient care. Because of the greater surface area to volume relationship, children are thought to be a greater risk of intraoperative hypothermia.

The most widely used method of maintaining body temperature during surgery (and a routine at this institution) is by using a forced-air warming blanket (Bair Hugger warming blanket, 3M). Despite its widespread use, the forced-air warming blanket has its limitations. For example, during certain surgical procedures, the location of the surgical field precludes placement of the warming blanket. In addition, the warming blanket often cannot be placed immediately after the induction of anesthesia (when complex patient positioning is required) - leaving the patient exposed to hypothermic conditions for short (10-15min) or long (30-60min) periods of time. There is hence a need for alternative warming systems that could be implemented immediately following anesthetic induction.

Westmed, Inc. has developed an alternative system that utilizes a heated, humidified breathing circuit to regulate a patient's body temperature in the intraoperative setting. This system is active from the moment the trachea is intubated following anesthetic induction, i.e. there are no delays in instituting thermal management.

Our goal is to evaluate the efficacy of the Westmed system vs the Bair Hugger Blanket.

2.0 Background

Significance of Research Question/Purpose: The Westmed Inc Anapod system used a humidified warming unit that is located within the anesthesia breathing circuit. The manufacturer has supported studies to evaluate the performance of the Anapod Humi-Therm Heated Humidification System Breathing Circuit in adult subjects. But while the system is being used nationwide in pediatric populations, there have been no studies in pediatrics, nor studies evaluating its performance compared to another well-established warming method (i.e. forced-air warming blanket).

Preliminary Data: The Anapod Humi-Therm Heated Humidification System Breathing Circuit has been evaluated in three studies

Seo et al., Effect of electrically heated humidifier on intraoperative core body temperature decrease in elderly patients: a prospective observational study, Anesthesiology and Pain Medicine 2016; 11: 211-216

Kaneyuki et al., A comparison of the effectiveness of transtracheal heating and humidification system in maintaining body temperature during general anesthesia with low flow gases, Masui. 2001 Jan;50(1):76-9

Bean et al., Active Humidification and Perioperative Temperature Regulation Using a Novel Heated Airway Circuit after Deep Hypothermic Circulatory Arrest, Society for Cardiovascular Surgery Annual Meeting poster, 2017).

All three of these studies demonstrated that the Anapod system was capable of preventing the development of intraoperative hypothermia. However, as noted, there are no studies evaluating the device in the pediatric population, nor have any of the aforementioned studied compared the Anapod system to other warming methods currently in use.

Existing Literature:

See above

3.0 Outcomes

Primary Endpoint/Outcome: Last measured core temperature at conclusion of the procedure (measured with rectal temperature probe) in patients assigned to the two warming systems.

Secondary Endpoint/Outcomes:

The need for hyperthermic or hypothermic rescue (see Section 5.0 for further explanation)

Cummulative degree-minutes above and below 37^{o}C in the two treatment groups (based on both 3M SpotOn and rectal temperatures.

Correlation of intraoperative 3M SpotOn temperature values with rectal temperatures.

4.0 Study Intervention(s)/Investigational Agent(s)

Description: This study will utilize the Anapod™ Humi-Therm Heated Humidification System Breathing Circuit from WestMed,and compare its efficacy in maintaining a patient's body temperature with an established warming method (Bair Hugger™ Warming Blanket).

Drug/Device Handling*:* The Anapod™ Humi-Therm Heated Humidification System Breathing Circuits will be stored in a separate section in the anesthesia equipment room. They will be clearly labeled "research use only, not for routine patient care". Anesthesia aides will set up the breathing circuit for study patients as directed by the study coordinator.

IND/IDE: N/A

Biosafety: N/A

5.0 Procedures Involved

Study Design*:* Prospective randomized non-inferiority study comparing Anapod™ Humi-Therm Heated Humidification System Breathing Circuit versus Bair Hugger™ Warming Blanket

Study Procedures*:* The study participants will be randomized to one of the following temperature management groups:

Group 1.) Anapod™ Humi-Therm Heated Humidification System Breathing Circuit, with a starting circuit temperature set at the standard 45°C (note, this is temperature at the unit - NOT the temperature of the gas reaching the trachea).

Group 2.) Bair Hugger™ Warming Blanket with a starting temperature set at HIGH

All aspects of anesthetic care will be as per routine except that a second temperature recording device will be used (3M SpotOn™ Forehead Temperature probe, used routinely in the operating rooms and postoperative recovery areas) in addition to the standard rectal thermister probe. In both groups, both Anapod™ and a BairHugger™ systems will be placed and ready for use prior to the induction of anesthesia. Randomization will occur immediately after anesthetic induction and endotracheal intubation.

For Group 1.), the BairHugger™ blanket will be connected a warming unit, but the unit will not be turned on. Patient warming will be provided via the Anapod™ system. In the event that the patient's rectal temperature falls below 35.6°C (96.08F), the BairHugger™ warming system will be activated ("Hypothermic Rescue"). In the event that rectal temperature increases to a value of ≥37.5°C (99.5), the Anapod system will be turned off - and the BairHugger turned on with the warming unit set to "ambient" (meaning cool operating room temperature will be blown over the patient ("Hyperthermic Rescue").

For Group 2, the BairHugger™ unit will be attached to the warming unit and started as soon as possible. In the event that the patient's rectal temperature falls below 35.6°C, the Anapod™ warming system will be activated ("Rescue"). In the event that rectal temperature increases to a value of ≥37.5°C (99.5°F), the BairHugger™ warming unit will be set to "ambient" (meaning cool operating room temperature will be blown over the patient ("Hyperthermic Rescue").

All drugs and devices required for participation:

A standard Bairhugger™ warming unit, an Anapod™ Humi-Therm Heated Humidification System Breathing Circuit, and two temperature measurement systems (rectal and SpotOn forehead)

Data to be collected about participants and the source records that will be used to collect those data:

From Epic: MRN, Name, Date of birth, Date of procedure, Height, Weight, procedure performed, and procedure duration. Preop Temperature (in preop area), Initial post-induction temperature (both rectal and SpotOn), final rectal and SpotOn temperatures prior to leaving the OR - as well as all rectal and SpotOn™ temperatures recorded intraoperatively, first PACU temperature (SpotOn only) Note: patient temperature data are recorded every minute in the Epic Anesthesia system and will be extracted from the record by manual record review.

Directly Collected (via research Case Report Forms): Warming device set-points, Rescue interventions (time and temperature when the rescue protocols are initiated.

Individually Identifiable Health Information: See above. PID including name, MRN, and other demographic information including date of procedure will be collected.

HIPPA Agreement: Attached

Use of radiation: None

Use of Center for Magnetic Resonance Research: N/A

6.0 Data and Specimen Banking

Specimen Banking: N/A

Data Banking: See above for all collected data. See below for data and data form handling

7.0 Sharing of Results with Participants

None

8.0 Study Duration

Individual Subject Participation Duration: For the duration of the dental procedure (typically 1-6 hours), from induction until discharge from the hospital.

Total Study Duration (all Participants): about 2 years

Total Study Duration Including Data Analysis: about 2.5 years

9.0 Study Population

Inclusion Criteria: Pediatric patients (ages 0-18 years) undergoing elective, scheduled dental procedures at Masonic Children's hospital requiring general anesthesia with endotracheal intubation, anticipated to last a minimum of 1hr. Procedures may include dental x-rays, dental exams, dental extractions, dental filling and dental restorations. Eligible procedures may last up to 6hrs or longer.

Vulnerable Populations: Children, Children with developmental delay, Children with behavioral disorders

Exclusion Criteria:

- Parent refusal of consent
- Patient refusal of assent (if applicable)
- Additional procedures (combined procedures) that involve other specialties besides dentists and other parts of the patient's body other than the oral cavity.
- History of diseases associated with temperature dysregulation (active hyperthyroidism, dysautonomia, osteogenesis imperfecta, history of malignant hyperthermia)
- Patients that will not be intubated for the procedure

Screening: Patients will be seen in dental clinic and scheduled for a dental procedure in the operating room. We will inform the dental clinic staff and make flyers available to patient families (flyer attached), which will introduce them to our study. Patients will be identified before the procedure by either the participating anesthesiologists or

research team by review of the posted operating room schedule (specifically by identifying the dental procedure list and the planned procedure). The research assistant responsible for discussing the research and obtaining the consent will call the patient's family the day before the procedure and determine whether they will consider participation. If the family expresses a willingness to consider participation, the research assistant or anesthesiologist will meet with the family on the day of the procedure to obtain consent and answer any additional questions.

10.0 Vulnerable Populations

Vulnerable Populations

☒ Children
☐ Pregnant women/Fetuses/Neonates
☐ Prisoners
☐ Adults lacking capacity to consent and/or adults with diminished capacity to consent, including, but not limited to, those with acute medical conditions, psychiatric disorders, neurologic disorders, developmental disorders, and behavioral disorders
☐ Approached for participation in research during a stressful situation such as emergency room setting, childbirth (labor), etc.
☐ Disadvantaged in the distribution of social goods and services such as income, housing, or healthcare
☐ Serious health condition for which there are no satisfactory standard treatments
☐ Fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior)
☐ Any other circumstance/dynamic that could increase vulnerability to coercion or exploitation that might influence consent to research or decision to continue in research
☐ Undervalued or disenfranchised social group
☐ Members of the military
☒ Non-English speakers
☐ Those unable to read (illiterate)
☐ Employees of the researcher
☐ Students of the researcher
☐ None of the above

Adults lacking capacity to consent and/or adults with diminished capacity to consent: None

Additional Safeguards: N/A

11.0 Local Number of Participants

Local Number of Participants to be Consented: 256

Basis for Sample Size Calculation: Since the BairHugger is the most widely used intraoperative warming system in used today (at UMN and around the country), this study is based on examining the non-inferiority of the Anapod system vs the BairHugger. A review of recent pediatric dental cases managed using the BairHugger shows an end-of-case rectal temperature median of 37°C (98.6°F), with an IQR of (36.9°F-98.4°F)-37.3°(99.2°F); means and SD are comparable (with a 95% CI for the mean of 36.9-37.1)98.7°F-. However, general clinical practice does not demand this kind of tight

control - and to construct a non-inferiority trial with a lower boundary of 36.9°C (98.4°F) would require an impossibly large sample size. We have therefore selected a non-inferiority boundaries of 0.3°C (32.54°F) , i.e. the Anapod would be considered "non-inferior" to the BairHugger if the mean end-of case temperatures were ≥36.6°C (97.8°F). For these conditions, a total sample of 256 patients (128 per group) are required to achieve and alpha of 0.05 and beta of 0.8.

12.0 Local Recruitment Methods

Recruitment Process:

Patients/families that are scheduled for procedures and willing to participate are invited to take part in the study. The research team will make attempts to contact the child's parent or guardian prior to the day of the procedure. The research team which also includes dentistry personnel, Dr. Soraya Beiraghi will try and speak with the patient and their family to consent them for the study at their dental visit prior to the procedure. If they decide to consent the dentistry staff will do so at that time. If they want to learn about the study at this visit and take the consent home for further consideration whether or not to participate, study personnel (from anesthesia) will contact the parents by phone on the day prior to the procedure to discuss their willingness to participate. Formal consent will then be obtained by direct conversation on the day of the procedure.

In addition, we have created a handout about the study to provide families in the dental clinic prior to their child's procedure. The researchers (PI from Anesthesia and study team from anesthesia) will have their contact information available on the brochure. Hopefully, they will have had time to review the handout and the consent so when the research team attempts to contact them before surgery, their questions will be answered. We will review the study again on the day of surgery.

Source of Participants: Dental surgery patients being performed on the West Bank of the University of Minnesota, Masonic Children's Hospital .

Identification of Potential Participants: Patients will be identified in dental clinic as far in advance as possible and by daily review of the surgical schedules in Epic.

Who will make initial contact with potential participants: Again, the Research team members will make attempts by phone to contact the parent or guardian to describe the study prior to the date of the procedure.

Recruitment Materials: Attached in Ethos

Payment: None

13.0 Withdrawal of Participants

Withdrawal Circumstances: Parents/Patients may withdraw from the study at any point prior to the induction of anesthesia by the principle investigator for any reason. At this point, the parents possibly will not be present (in the OR) and the patient will be unconscious. If this is the case the research team will inform the family immediately.

Withdrawal Procedures: Group randomization will take place immediately after anesthetic induction. If a parent/patient withdraws after providing consent but prior to the induction of anesthesia and randomization, no further data will be collected (and any data forms started prior to induction will be destroyed).

Termination Procedures: *the Principle investigator has the right to terminate the study at any time during the study.*

14.0 Risks to Participants

Foreseeable Risks:

Overall, the proposed study does not carry any identifiable risks for patients beyond those normally encountered with anesthesia and surgery. Both the BairHugger and Anapod systems are approved for clinical use and are being used for their approved and marketed purposes. There is a potential for both devices to result in unintended hyperthermia - but since body temperature is monitored and recorded continuously, and because Rescue Protocols are in place for all patients, body temperatures outside of the desired ranges ($\leq$35.6°C and $\geq$37.5°C) will be prevented or corrected quickly. NOTE: this attention to close temperature maintenance EXCEEDS what is done during routine care.

The Anapod™ Humi-Therm Heated Humidification System Breathing Circuit uses warmed, inspired air to warm the patient. It is theoretically possible that the device might malfunction, resulting in excessively warmed inspired gases and airway injury. However, the device has passed extensive safety testing and has built in safety systems (which shut down the warming system if excessive temperatures are noted). The device will be used only in its FDA approved manner according to all manufacturer specifications and directions. To date, no such failures have been reported to the manufacturer.

Reproduction Risks: None

Risks to Others: None

15.0 Potential Benefits to Participants

Potential Benefits: Participation will not have any direct benefit for the subject.

16.0 Data Management

Data Analysis Plan: *Describe the data analysis plan, including any statistical procedures.*

Our primary outcome variable is the patient's rectal temperature at the end of the surgical procedure. Since this is a continuous and generally normally distributed variable, intergroup comparisons will be via a simple unpaired t-test.

Our primary secondary variable will the incidence of hypothermia and hyperthermic rescue which will be compared between groups via a 2 x 2 Chi-Square Test (or depending on numbers, a Fisher's Exact Test) [Hypo and Hypothermic Rescue, Yes/No for the two groups).

Cummulative degree-minutes below or above our target values are again expected to be a continuous, normally distributed value and hence can be tested by t-test.

The relationships between rectal and Spot-on intraoperative temperatures will be examined by both correlation analysis (linear regression) and via a repeated-measures Bland-Altman method.

Data Integrity: Objective data will be digitally collected from the EMR and extracted by members of the research team. These extracted data, as well as protocol compliance and the incidence of Rescue interventions will be reviewed by the PI or Co-PI each week. A detailed review of all patients collected to date will be conducted in monthly intervals by the PI. Group assignment will be blinded with the data set (Group A vs B) for review purposes - although it is important to note that true blinding of the providers (including on PI and Co PI) is impossible for this procedural study.

17.0 Confidentiality

Data Security: Only the core study team (PI, Co-PI, support personnel) will be handling PHI during the initial collection process. Data will be collected on paper forms. Each paper form will be given a code number. When data are transferred into REDCap (for later analysis) ONLY this code number will be included. The PHI which might be connected with a specific patient (e.g name, MRN, date of surgery) will be placed in REDCap on a separate data sheet that will include the study number so that if necessary for data correction purposes we can go back and verify our data. The source documentation and consent documents (with identifying information) will be stored in a locked cabinet in the locked research office - accessible only to the core study team.

18.0 Provisions to Monitor the Data to Ensure the Safety of Participants

Data Integrity Monitoring:

As noted above, a detailed review of all patients/patient data will be conducted at monthly intervals by the PI or Co PI, to insure that all required information is being captured correctly. Any missing data or unexplained "out of range" data will immediately trigger a

detailed review of the source data (Epic) and the RAs will be re-educated as to correct procedures to minimize the chance of recurrence. The PI or Co PI will also review the Epic records of EACH patient to verify that the designated protocols were followed - in particular whether any "rescue" interventions were implemented correctly (i.e. at the correct trigger temperatures).

Any adverse events occurring in any patient - whether or not related to the study or to temperature management - will be reported to the study team (or, if not reported, will be captured by case-by-case chart reviews). An adverse event log will be maintained and events will be reported to the IRB. If there is any question as to whether the event was related to the study, the case will be referred to Dr. Michael Todd, the Department of Anesthesiology's Vice Chair for Research and the Departments Quality Assurance Event monitor, for review and adjudication. Dr. Todd will be empowered to temporarily halt enrollment if any safety concerns are noted - although the final decision re. halting or resuming the study will be referred to the Departments DSMB.

Data Safety Monitoring: The Department of Anesthesiology has a designated "DSMB" headed by Dr. Joyce Wahr and including Drs. Richard Prielipp and Michael Todd. Given the low risk nature of this study, our plan is for the DSMB to receive blinded (A vs B) data after the completion of the 128th patient (the half-way point). While statistical stopping rules for non-inferiority studies remain uncertain, we will use a well-established O'Brien-Fleming procedure and will stop the study if the SUPERIORITY of either method is established, based on an intergroup Z-score difference of 2.78.

19.0 Provisions to Protect the Privacy Interests of Participants

Protecting Privacy: Patients/ families will be provided written information about the study and contacted by phone to assess their willingness to participate, hence minimizing the amount of direct interaction until the decision is made to participate. The patient/ family will interact directly with the research assistant who will obtain consent and collect data. After the procedure is concluded, there is no planned additional follow-up. The collected information will be handled according to HIPPA rules and regulations as detailed before.

As noted above, all data gathered in the course of the study, other than the paper forms completed at the time of surgery, will be coded and constructed in such a way as to eliminate all patient identifiers.

Access to Participants: Review of the child's Epic anesthesia record is required for the successful completion of this study. Patients/ families will be consented and will give permission for the research team to use specifically defined information.

20.0 Compensation for Research-Related Injury

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed

in the ordinary manner to the subjects insurance. Under some circumstances the sponsor of the study will pay for care for injuries resulting directly from being in the study. If the child's parent or guardian want information about those circumstances or if they think their child has suffered a research related injury let the study physicians know right away.

21.0 Consent Process

Consent Process: Attempts will be made to try and contact the patients parents or guardian with written information prior to the procedure. The research team, which also includes dentistry personnel (Dr. Soraya Beiraghi and reseach staff) will try and speak with the patient and their family at the initial dental visit prior to the procedure. If the parents decide to consent they will do so at that time. If they want to learn about the study at this visit and take the consent home to further evaluate whether or not to participate, study personnel (either from dentistry or anesthesia) will contact the parents by phone on the day prior to the procedure to discuss their willingness to participate. If the parents decide to participate, formal consent will be obtained by direct conversation on the day of the procedure. The study staff will explain the differences between the system we are studying and the standard of care (BairHugger). We will have pictures of both systems to facilitate the discussion. We will also emphasize that for patient safety, the study requires the placement of both systems at the beginning of the dental procedure so that the Bairhugger warming-blanket (standard of care) serves as a back-up in case the studied system is unable to maintain body temperature. The randomization process will inform the physician which system will be used as a primary warming device. The standard of care rectal temperature probe will also be placed in all children to monitor their temperature throughout the case. If the system assigned is not performing optimally, the physician can choose to switch to the other system. The research staff will be present and decisions will be thoroughly discussed; any changes will be documented in the subject's chart.

Waiver or Alteration of Consent Process: N/A

Non-English Speaking Participants: Patients with any primary language will be considered for inclusion, so long as there is a professional interpreter available for the consent process and other aspects of the study. The study is not targeting any subjects that have a specific language. The short form will be used if the subject is non-English speaking.

Participants Who Are Not Yet Adults: See above. This is a pediatric study. Ninety Percent of the dental cases performed under anesthesia are under the age of 7. The capability of these children (taking into account the ages, maturity and psychological state of the children involved) is so limited that they cannot reasonably be assented. For children aged 7 years and above, the majority of participants have neurodevelopmental conditions that impact cognition and behavior. They will be undergoing medically necessary dental procedures under anesthesia with parental consent, where child assent is not obtained. It is in our clinical judgment that to attempt to obtain

assent for this study might cause the child unnecessary confusion, emotional upset and harm, when they have not been allowed to refuse the medical procedure itself. In these cases, we will obtain parental/LAR consent only, and document the underlying diagnosis. For the few cases where there is no neurodevelopmental condition, we will obtain child assent for the study

Cognitively Impaired Adults, or adults with fluctuating or diminished capacity to consent:

Not Eligible

Adults Unable to Consent: Not Eligible

22.0 Setting

Research Sites:

- Dental procedures are performed in the surgical suites at the University of Minnesota West Bank medical center (Masonic Children's Hospital)
- Data analysis will be conducted in the Anesthesiology offices at the East Bank (Mayo building) and by the Department of Anesthesiology's statistician (Alex Kaizer PhD)

23.0 Multi-Site Research N/A This study is only being conducted at the University of Minnesota

24.0 Resources Available

Resources Available: Research Assistants to aid in consent and data acquisition.

Available Patients: During a typical week at the West Bank Medical Center, approximately 10-20 qualifying patients undergo appropriate elective dental surgery. Note however, that logistics will probably limit us to enrolling at maximum of 2 patients on any given day.

Time to Devote: We anticipate this will require approximately 10-20% effort on the part of the principle investigator. This will also require 50% -75%effort of a research assistant's effort.

Describe your facilities: All procedures will be performed in the clinical facilities of M Health West Bank operating room arena. Data storage and analysis can be done using desktop equipment which is available in the Research Office located on the East Bank Mayo Memorial Building. This office is locked at all times with only research staff having access. Data will be stored on the university-supported secured Box cloud storage drive. Only the research staff and PI will have access to the Box.

Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions: RAs and other support faculty will be trained by the principle investigator (Kloesel) and the

Co-PI (Belani). Training will include a review of the protocol, consent form and data collection forms as well as hands-on instructions on the used devices.

25.0 References

Seo et al., Effect of electrically heated humidifier on intraoperative core body temperature decrease in elderly patients: a prospective observational study, Anesthesiology and Pain Medicine 2016; 11: 211-216;

Kaneyuki et al., A comparison of the effectiveness of transtracheal heating and humidification system in maintaining body temperature during general anesthesia with low flow gases, Masui. 2001 Jan;50(1):76-9;

Bean et al., Active Humidification and Perioperative Temperature Regulation Using a Novel Heated Airway Circuit after Deep Hypothermic Circulatory Arrest, Society of Cardiovascular Anesthesiologists annual meeting poster, 2017

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