Cooper University Hospital

INFORMED CONSENT AND HIPAA AUTHORIZATION TO PERMIT THE USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH PURPOSES

TITLE OF STUDY: Optimal Warming Strategies to Reduce the Incidence, Duration and Depth of Intraoperative Hypothermia: a Prospective Randomized Non-Blinded Clinical Trial

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SPONSOR: Augustine Medical

SUBJECTS NAME: _____

What does the research study involve?

You are being invited to take part in a research study. Please read this form carefully, it will give you information to help you decide if you want to volunteer (you choose to take part) for this research study. You do not have to take part in this study to receive treatment at Cooper Hospital. The study doctor and his staff will discuss with you what is involved in this research study. If you decide to take part, you and the study doctor or a member of the study team will sign this consent form. You will receive a copy of this consent form to keep. If you have questions at any time during the research study, you should feel free to call any of the doctors listed above and ask your questions until you receive answers that satisfy you.

Who is paying for this research and where is it being done?

This study is being carried out solely at Cooper University Hospital. It is sponsored by Augustine Medical.

What is the purpose of this research study?

General and regional anesthesia can cause unintended low body temperature. Lower body temperature is associated with several adverse effects such as: bleeding, increased risk of infection, irregular heartbeats, and increased hospital length stay. Therefore, it is important to maintain a patient's temperature above 36° C (96.8° F) during surgery. The purpose of this study is to determine the effectiveness of two warming devices that are used every day at Cooper University Hospital during surgery, and the best strategy for maintaining your body temperature during surgery within normal limits. Another purpose of the study is to investigate if warming with these devices before surgery, in addition to during surgery, can improve temperature control during surgery.

The two warming devices that will be used are the HotDog system and the Bair system. The HotDog works similar to an electric blanket whereas the Bair system works by blowing warm air into an air mattress.

The HotDog warming system consists of four primary, FDA approved, components:
- Warming Blanket,
- Warming Pad (Mattress),
- Connecting Cables, and a
- Temperature Controller

The Bair warming system consists of the following, FDA approved, components:
- Portable Forced-Air Temperature Management Unit, and
- Disposable Bair Hugger Forced-Air Blanket

How long will the study take and how many people will take part?

A total of 184 subjects will be enrolled in this study. Your participation in the study will start from the day of surgery and end 30 days after.

What will you be asked to do if you take part in this study?

If you decide to participate, you will be assigned at random (like flipping a coin) to one of four warming plans:

Group 1: Pre-warming with a HotDog system for at least 30 minutes & the HotDog system during surgery.
Group 2: Pre-warming with Bair system for at least 30 minutes & the Bair system during surgery
Group 3: No pre-warming device. Warm blankets upon request for pre-warming. HotDog system during surgery
Group 4: No pre-warming device. Warm blankets upon request for pre-warming. Bair system during surgery

Details of warming plan per group:

Warming plan in **Group 1:** If you are assigned to be in Group 1 you will be pre-warmed with the Hotdog Warming System in the preoperative area. You will have a HotDog warming blanket placed on your lower body in the preoperative area. The warming blanket will be set to 43 °C (or 109.4 °Fahrenheit) and will be used for at least 30 minutes before you go to the operating room. Once in the operating room, a HotDog warming pad (mattress) will be on the operating table underneath you. The underbody pad will be pre-heated to 39 °C (or 102.2 °Fahrenheit). The operation room staff will place a HotDog warming blanket over you after you have been brought to sleep by the anesthesia team. The blanket will be placed on your upper or lower body type depending on the type of surgery and will be set to 43 °C (or 109.4 °Fahrenheit).

Warming plan in **Group 2:** If you are assigned to Group 2 you will be pre-warmed in the preoperative area with the Bair system. A disposable Bair Hugger Forced-Air lower body blanket will be placed on you. The blanket is connected to the Portable Forced-Air Temperature Management Unit that blows warm air into the blanket. The blanket will be set to 43 °C (or 109.4 °F) for at least 30 minutes before you are being transferred to the operating room. In the operating room an upper or lower body Bair Hugger blanket (depending on the type of surgery)

will be placed on you after you have been brought to sleep by the anesthesia team. The blanket will be set to 43 °C (or 109.4 °F).

Warming plan in **Group 3:** If you are assigned to Group 3 you will be given a pre-warmed regular blanket to cover your body in the preoperative area. You may decline the warm blanket if you do not want it. Once in the operating room, a HotDog warming pad (mattress) will be on the operating table underneath you. The underbody pad will be pre-heated to 39 °C (or 102.2°Fahrenheit). The operation room staff will place a HotDog warming blanket over you after you have been brought to sleep by the anesthesia team. The Hotdog blanket will be placed on your upper or lower body type depending on the type of surgery and will be set to 43 °C (or 109.4 °F). The regular pre-warmed blankets you may receive in the pre-operative area are heated the same as if you are in the study or not in the study.

Warming plan in **Group 4:** If you are assigned to Group 4 you will be given a pre-warmed regular blanket to cover your body in the preoperative area. You may decline the warm blanket if you do not want it. In the operating room an upper or lower body Bair Hugger blanket (depending on the type of surgery) will be placed on you after you have been brought to sleep by the anesthesia team. The blanket will be set to 43 °C (or 109.4 °F). The regular pre-warmed blankets you may receive in the pre-operative area are heated the same as if you are in the study or not in the study.

We will measure your body temperature several times before surgery and after surgery using an oral thermometer. During surgery we will measure your body temperature using a temperature probe in your esophagus (tube going form the mouth to the stomach). One day after surgery we will ask you some questions regarding how satisfied you were with the used warming treatment.

Someone from the study team will call you 30 days after your procedure to conduct a follow-up interview over the phone. They will ask you if you have had any medical related problems and/or if you were admitted back to Cooper University Hospital, or any other hospital, since your surgery.

From your medical record we will record information about you such as your age, height, weight, details from your surgical procedure, and information about any incidence of complications such as unexpected bleeding, blood transfusion, cardiac arrhythmia (irregular heart beat), infection within 30 days after surgery, and any readmissions up to 30 days after surgery. We will also collect how long you stayed in the hospital.

Who may or may not take part in this study?

You are being asked to take part in this study because you are over the age of 18 and are scheduled to have either elective abdominal, gynecologic, breast, plastic/reconstructive or urologic surgery under general anesthesia.

What risks are there?

A potential risk may be that one or more of the four warming plan options may be worse at preventing a low body temperature during surgery than one or more of the other warming plan options.

A rare complication from using the Bair warming system are burns, when the warming blanket is used while an arm or leg is not well perfused (how well blood flows to tissue in the arm or leg)

with blood. Low blood perfusion (blood flow) typically happens during cardiac surgery and cardiac surgery patients cannot participate in this study.

The study team will share the results of this study with the sponsor. Your study files will be de-identified, meaning that all identifiable information (like name, addresss, telephone number, etc.) will be redacted/deleted and will only be marked with only your unique study number. There is a potential risk for loss of confidentiality if one or more of your identifiable information in your study files is mistakenly or unintentionally, not redacted/deleted.

There may be unforeseen risks associated with participation.

What benefits are there?

There may be no benefit from participating.

A benefit may be that one or more of the four warming strategies may be better at preventing a low body temperature during surgery than one or more of the other strategies. In addition, what we learn from the study may benefit other people in the future.

What are your alternatives (other choices) if you do not take part in this study?

If you decide not to take part in this study, your doctors may still give you the option of being pre-warmed prior to your procedure with either the HotDog warming system, the Bair warming system, or just with a warm blanket. You could still have one of the listed devices above used in the operating room to warm your body during surgery. The doctors and surgeons associated with your care would select which device they will use during your surgery. We would not record any study information pertaining to these devices and their outcomes if you decided not to participate in the study.

How will information about you be kept private?

To help maintain the confidentiality of your study records, you will be assigned a subject number. All of your study related-information will have only your subject number. Identifying information, like your name, address, and telephone number, will be linked to your subject number but will be kept separate from your study-related information. Your study documents will be stored in a locked file cabinet. The information from this study may be published in scientific journals or presented at scientific meetings but you will not be personally identified in these publications and presentations.

When can your participation be terminated by the investigator?

The investigator may terminate your participation in the study if you are not able to have the warming device applied in the perioperative area.

Are there any other costs?

There are no costs to you from participating in this study.

Will you be paid for participation?

You will not be compensated (paid) for participating in this study.

What will happen if you become sick or hurt because you are in this study?

If you are injured as a result of taking part in this research study, you will be given the medical care that you need, but it will not be free. Your insurance will be billed for the medical treatment. You will be billed for the costs your insurance does not cover. There are no provisions to provide any other form of compensation. That does not mean that you are giving up any of your legal rights.

If you believe that you have been injured or become ill because you took part in this study, you should call the Chief Medical Officer or his representative at (856-342-3071).

What will happen if you withdraw?

Tell the investigator if you want to withdraw from the study. Your data from be removed from the study. If you decide not to participate or to drop out of the study, your decision will not affect your care at Cooper Hospital either now or in the future. If you decide to quit the study, please contact the study doctor before the surgery.

Will you be told about new information that might affect your decision to take part in this research?

During the study, you will be told if any new information is learned that could affect your willingness to stay in the study.

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USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH PURPOSES

Will your information be kept confidential?

The privacy regulations of a law passed by Congress became effective on April 14, 2003. The law is called the Health Insurance Portability and Accountability Act, HIPAA for short. The law gives subjects in research studies certain rights about their protected health information. Protected health information (PHI) is information about a person's physical or mental health that can be identified with or linked to that particular person. If you sign this form you are giving the investigators, their staff, and certain other people described in this form your permission to use your protected health information for this research study.

The information collected about you for this study is called "protected health information" (PHI). It includes: demographic information (e.g., your name, address, etc.), medical history, your answers to the study questionnaire, results of measurements that were done for this study, and the results of tests and procedures that are being done for your treatment.

All of this information is being collected because you are participating in this research study.

Information about you will also be collected from your medical records that are located in Cooper University Hospital's medical records department. The information that is collected will be used to decide if you qualify to participate in this research, to follow your treatment, and will be analyzed to answer the research questions.

By signing this form, you are allowing the following people or groups to have access to the information described above (your PHI).

The research team, which includes the investigators listed on this form and other personnel involved in this specific study need to analyze the data.

Cooper's Institutional Review Board (IRB), a committee that reviews, approves, and monitors research involving human subjects may look at your study records.

Other people who work for the CHS or its affiliated health care providers may look at your health information for the following reasons: (1) They need to fulfill orders (made by the investigators) for hospital and health care services (e.g., laboratory tests, diagnostic procedures) related to your being in the research study. (2) They need to address correct payment for tests and procedures ordered by the investigators. (3) They need to perform internal hospital operations (e.g. quality assurance)."

All of these people and entities are obligated to protect your PHI.

Other people who work for the CHS or its affiliated health care providers may look at your health information for the following reasons: (1) They need to fulfill orders (made by the investigators) for hospital and health care services (e.g., laboratory tests, diagnostic procedures) related to your being in the research study. (2) They need to address correct payment for tests and

procedures ordered by the investigators. (3) They need to perform internal hospital operations (e.g. quality assurance).

You are also allowing your PHI to be shared with other people or groups specified below:

Augustine Medical, the company that is paying for the research as they need to be sure the records are accurate. To do this they will analyze the research data. Augustine Medical is the manufacturer of the HotDog warming system.

Although these entities listed above have their own confidentiality procedures to protect your PHI, they are not covered by the same federal privacy rule (the Health Insurance Portability and Accountability Act of 1996, or HIPAA) that governs healthcare providers, and therefore they are not bound to its regulations.
In unusual cases, an order from a court of law may require the investigators to release your health information. This information may include your study records and other medical record information. State law may require the investigators to inform the appropriate agencies if the investigators learn that you or someone with whom you are involved is in serious danger or potential harm.

You may already have a copy of CHS's Notice of Privacy Practices. If you do not have one, the investigator will give you one. You have the right to limit the use and sharing of your PHI, and you have the right to see your research study records and know who else is seeing them. You will not be allowed to see your health information that is created or collected during the course of the research. After the research is finished, however, you may see this information.

You are authorizing us to use and disclose your PHI until the end of the research study. You may revoke this authorization to use and share your PHI at any time by contacting the principal investigator, in writing, at the address on the front of this form. If you decide not to authorize the investigator to use and disclose your PHI or you revoke this authorization, you will no longer be able to participate in this research study, and the use or sharing of future PHI will be stopped. However, the PHI that has already been collected may still be used.

If you decide not to allow the investigators to use and disclosure your health information for this research study it will not affect your care at CHS, its affiliated health care providers, or hospitals now or in the future.

<u>Whom can you contact if you have a question?</u>
If you have any questions about this research, you can contact the principal investigator at the number on the first page.

You should call the Chief Medical Officer or his representative at (856-342-3071) (a) if you have any questions about your rights as a research subject or your rights related to the research use of your PHI, (b) if you believe that you have not been told about all the risks, benefits, and alternative treatments, (c) if you believe that you are being forced to stay in this study when you do not want to, or (d) you have any complaints about the research.

You should also contact that person if you believe that you have not been adequately informed as to the risks, benefits, or alternative procedures of this research study, or that you are being pressured to participate in the study against your wishes.

If you have any questions about the research or your rights as a subject or any complaints about the research, you may also contact the Institutional Review Board (IRB) of the Cooper

Health System. The IRB is responsible for protection of subjects participating in this research project. The address of the IRB is E&R Building, 401 Haddon Ave., Room 288, Camden, NJ 08103. The phone number is 856 757-7832.

CONSENT STATEMENT

Your participation and your decision to allow the use of your PHI are entirely voluntary. You do not have to participate or let us use your PHI. If you decide not to participate or not to let us use your PHI or you decide to stop participating or to stop letting us use your PHI, it will not affect your treatment at Cooper University Hospital. Your doctors will continue to treat you the way they always have.

All of the above has been explained to me. All of my questions have been answered. I can ask questions that I have about the research or about the use and disclosure of my PHI at any time. My questions will be answered by one of the investigators listed on the first page of this form.

By signing this form I agree to participate in this study and I agree to the use and disclosure of my PHI for the purposes described above. A copy of this form will be given to me.

Printed Name of Subject:

Signature: _____ Date: _____ Time:

WITNESS
Printed Name of Witness to Subject's Signature:

Signature: _____ Date: _____ Time:

I have discussed the study described above with the subject.

Printed Name of Person Obtaining Consent: _____

Signature: _____ Date: _____ Time: