Transesophageal echocardiography (TEE) to guide and confirm epidural catheters in pediatric patients

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INFORMED CONSENT DOCUMENT

Project Title: **Transesophageal echocardiography (TEE) to guide and confirm epidural catheters in pediatric patients**

Principal Investigator: **Kenichi Ueda, MD**
Research Team Contact: [redacted]

- If you are the parent/guardian of a child under 18 years old who is being invited to be in this study, the word "you" in this document refers to your child. You will be asked to read and sign this document to give permission for your child to participate.
- If you are a teenager reading this document because you are being invited to be in this study, the word "you" in this document refers to you. You will be asked to read and sign this document to indicate your willingness to participate.

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you are scheduled to undergo cardiothoracic surgery or a procedure that uses special machines to help your heart also known as interventional cardiology diagnostic procedures under general anesthesia followed by a chest x-ray. During your surgery, a machine called a transesophageal echocardiogram (TEE) will be used to take pictures of your heart. The TEE will be controlled byyour anesthesiologist (a doctor that helps you sleep during surgery) or your cardiologist (a doctor who takes care of your heart), and is part of your planned surgery.

In order to help you sleep in surgery, your anesthesiologist is going to put a small tube, called an epidural catheter, a pain control device, into your back so you don't feel any pain. This is standard procedure in your surgery and will happen regardless of your participation in this study.

The purpose of this research study is to determine if the rotated TEE probe can be used to help with the placement of this epidural catheter (pain control device). By allowing us to use the TEE probe to help guide the placement of this tool, we think we can determine the exact location that we are putting this pain control device. This study may help us determine if the TEE machine can be used as a tool in the future to help doctors guide epidural catheters to the correct position in the spine.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 25 people will take part in this study conducted by investigators at the University of Iowa.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for the length of your surgery. The study itself will take approximately thirty minutes prior to surgery but this will not affect the surgery itself in any way. Because the study will occur as you are being prepared for surgery, it will not lengthen your time under anesthesia or your time in the operating room. Your participation will not affect your length of stay in the hospital.

WHAT WILL HAPPEN DURING THIS STUDY?

We will obtain and use information from your health records for this study, such as your height, weight, age, sex, clinical diagnosis, heart rate, blood pressure, information about your blood, any known history of esophageal abnormalities, lesions or disease, current procedure, pain score after surgery in the post-anesthesia care unit and total morphine used within 24 hours after surgery.
No additional information will be added to your medical record chart.

On the day of surgery, you will come to the operating room and you will be prepared for your surgery as usual. No additional preparations are needed for this study. The pre-surgical procedures will be discussed with you by your anesthesiologist and surgeon. The anesthesiologist will then place a small probe the size of a straw through your mouth and down your throat to take pictures of your heart (this is the TEE machine); this is standard procedure in these surgeries and will occur regardless of participation in this research study. As part of this study, the probe will also be guided to view the spinal cord and back and we will attempt to see an epidural catheter as it is being placed by another trained anesthesiologist. This will take approximately thirty minutes as you are being prepared for surgery, then, surgery will proceed as normal.

The study procedure will occur while you are asleep in the operating room while you are being prepared for surgery by the anesthesia team. It will not increase your length of time under anesthesia or your time in the operating room because this catheter device will be put in regardless of your study participation. No long-term follow up or data collection will be necessary. When you leave the operating room you will undergo an x-ray to image the heart and the catheter placement. This is standard procedure and will occur with or without participation in this study. Once the x-ray has been taken, nothing additional is required.

Data Storage for Future Use

As part of this study, we are obtaining data from you. We would like to study your data in the future, after this study is over.

The analysis we might want to perform on your data may not be known at this time. Therefore, we are asking for your permission to store your data so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding if this TEE machine can be used in future studies to help place epidural catheters (pain control devices) in the spine before surgery, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your data might be used to develop products or tests that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.

If you agree now to future use of your data, but decide in the future that you would like to have it removed from future research, you should contact [redacted]. However, if some research with your data has already been completed, the information from that research may still be used.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.
Because TEE (transesophageal echocardiogram) will be used while you are asleep, there will be no additional discomfort produced by your involvement in this study. Your doctor will need to use TEE to care for you while you are in surgery. Therefore, the only additional physical risk to you is in the additional movement of the TEE probe within the esophagus (throat) if you agree to participate. TEE has a very low risk of injury associated with its use and will be used to look at your heart regardless of your participation in this study. No aspect of the surgery itself will be changed by this study and the same risks would be in place if you were not in the research study. No additional time will be required because the placement of the pain control device would occur with or without guidance by the TEE machine.

There is a small risk of loss of confidentiality. Measures in place to protect subject confidentiality are noted in the 'What About Confidentiality' section later in the document.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study. However, we hope that, in the future, other people might benefit from this study because the knowledge gained may be useful in helping physicians in future surgeries.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional costs for being in this research study.
You and/or your medical/hospital insurance carrier will remain responsible for your regular medical care

expenses.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

The University and the research team are receiving no payments from other agencies, organizations, or companies to conduct this research study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
- The University of Iowa does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.
- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will keep all information from this study in locked offices or in password-protected computer files. Further, your patient information will be given a unique identification number that will not link directly to you. Any hard copy records or paper records will also receive a matching identification number at the earliest time possible and patients will be identified by such for the duration of the study. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

The University of Iowa Hospitals and Clinics generally requires that we document in your medical record chart that you are participating in this study. The information included in the chart will provide

contact information for the research team as well as information about the risks associated with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires University of Iowa Health Care to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study. Once University of Iowa Health Care has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff.

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes University of Iowa Health Care to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to [redacted] However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please

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contact: [redacted]. If you experience a research-related injury, please contact: [redacted].

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://research.uiowa.edu/hso. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

Do not sign this form if today's date is on or after $STAMP_EXP_DT.

_____ _____

(Signature of Subject) (Date)

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Parent/Guardian 's Name and Relationship to Subject:

_____ _____
(Name - printed) (Relationship to Subject - printed)

Do not sign this form if today's date is on or after **$STAMP_EXP_DT.**

_____ _____
(Signature of Parent/Guardian) (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)