Transesophageal echocardiography (TEE): A novel technique for spinal cord imaging

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Transesophageal echocardiography (TEE): A novel technique for spinal cord imaging

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IRB ID #: 201206753

Form Content

I. Project Introduction

I.1 ***Project to be reviewed by:***
IRB-01

I.2 ***Project Title:***
Transesophageal echocardiography (TEE): A novel technique for spinal cord imaging

I.3 ***Short Title (optional):***

I.4 ***Provide a short summary of the purpose and procedures of the study proposed in this IRB application.***

- ***DO NOT include information on studies not proposed in this application.***
- ***Use LAY terminology only. This must be easily understandable by IRB community members and nonscientists.***
- ***DO NOT cut and paste technical abstracts from funding applications that may not be understood by a general audience.***

The aim of this prospective observational study is to assess whether transesophageal echocardiography (TEE) can be used to identify the structures within the vertebral foramen of the spinal column and to determine the range of spinal segments which can be visualized. Data will be collected from both pediatric and adult patients undergoing cardiothoracic and interventional cardiac surgeries under general anesthesia. Because use of TEE is a standard surgical procedure and because TEE will already be in place to visualize the heart, no additional processes will be required to collect data, minimizing patient risk. TEE will be monitored and controlled by a trained anesthesiologist or TEE technician and visualization of the spinal cord will be confirmed. Real-time TEE images will then be captured and later graded by a trained sonographer as high, medium or low quality. Starting at the level of the tracheal bifurcation, corresponding to thoracic vertebral level T5 (Mirajalili 2012), the TEE probe will be advanced cranially to determine the spinal levels visualized above T5 and caudally in order to determine the spinal levels below T5 that can be seen on TEE. At each level seen on TEE, pictures will be taken for confirmation.

I.5 ***Specify your research question(s), study aims or hypotheses (do not indicate "see protocol")***
The primary outcome is to identify the spinal column and epidural space on real-time TEE image, as well as to determine the range of spinal segments that can be visually spanned by TEE.
The secondary outcomes include classification of the captured TEE image as high, medium or low quality as determined by a trained sonographer.
H0: The null hypothesis is that the spinal cord and epidural space will not be visualized on real-time TEE image.
H1: The alternative hypothesis is that the spinal cord and epidural space will be successfully confirmed by real-time TEE image in all individuals.
To test this hypothesis, both pediatric and adult patients undergoing cardiothoracic or interventional cardiac surgeries under general anesthesia will be included in the study population.

I.6 ***Background and significance and/or Preliminary studies related to this project. (do not indicate "see protocol")***
Transesophageal echocardiography is a semi-invasive, monitoring and analytic tool used to generate reproducible images of the heart and mediastinum. TEE is routinely used in cardiothoracic and interventional surgeries as well as in detecting thromboses, valvular defects and congenital heart disease. There has been expanding utilization of TEE outside of cardiac surgery as a potential haemodynamic monitor both intraoperatively and postoperatively (Pissarra 2012). While TEE is not regularly used to visualize the spinal column, it can be done with relative ease when consciously attempted (Chitilian 2006). To our knowledge, this prospective observational study will be the first attempt to deliberately image the structures within the vertebral foramen, to scan the spinal segments identified by TEE and to classify the TEE image quality by a trained sonographer. Given the nearly universal use of TEE in cardiac surgical operating rooms, in combination with the low risk of complications(Daniel 1991), potential outcomes include the use of TEE in the placement of thoracic epidural catheters, in identification of spinal cord trauma or as a monitor of intraoperative perfusion and pressure surrounding the spinal cord (Godet 1994). This could lead to improved precision, success and safety of regional anesthesia.

I.7 ***Literature cited / references (if attaching a grant or protocol enter N/A).***
1. Pissarra F, Oliveira A, Marcelino P: Transoesophageal echocardiography for monitoring liver surgery: data from a pilot study. Cardiology research and practice 2012, 2012:723418.
2. Chitilian HV, Alston TA, Avery EG: Transesophageal echocardiographic bull's eye. Journal of cardiothoracic and vascular anesthesia 2006, 20(6):894-895.
3. Daniel WG, Erbel R, Kasper W, Visser CA, Engberding R, Sutherland GR, Grube E, Hanrath P, Maisch B, Dennig K et al: Safety of transesophageal echocardiography. A multicenter survey of 10,419 examinations. Circulation 1991, 83(3):817-821.
4. Godet G, Couture P, Ionanidis G, Gosgnach M, Kieffer E, Viars P: Another application of two-dimensional

transesophageal echocardiography: spinal cord imaging. A preliminary report. Journal of cardiothoracic and vascular anesthesia 1994, 8(1):14-18.

II. Research Team

II.2 ***Team Members***

UI Team Members

Name	E-mail	College	Contact	Key Prsn	UI COI	VAMC COI	Consent Process Involvement	Deactivated
Kenichi Ueda, MD								

Non-UI Team Members

Name	Institution	Location	FWA	Role	DHHS Contact	Key Prsn	UI COI	VAMC COI	Consent Process Involvement	Email
Nothing found to display.										

II.3 ***The Principal Investigator of this study is:***
Faculty

III. Funding/Other Support

III.1 ***Funding Sources***

Type	Source	Grant Title	Name of PI on Grant
Departmental / PI Discretionary			

* new source name

III.3 ***Does any member of the research team have a financial conflict of interest related to this project according to the Conflict of Interest in Research policy? If yes, please indicate which membersbelow.***

Name	Has Conflict of Interest
Kenichi Ueda, MD	No

Do you want the IRB to give this project
Regular (expedited or full board) review

IV. Project Type

IV.1

IV.2 ***Enter the date you will be ready to begin screening subjects/collecting data for this project. (If you do not have a specified date, add "upon IRB approval")***
6/25/2012

IV.3 ***Are you requesting a waiver of informed consent/authorization (subjects will not be given any oral or written information about the study)?***
No

V. Other Committee Review

V.1 ***Does this project involve any substance ingested, injected, or applied to the body?***

- ***Do not answer yes, if the involvement includes a device, wire, or instrument***

No

V.2 ***Are any contrast agents used for any purpose in this study?***
No

V.9 ***Will any subject be asked to undergo a diagnostic radiation procedure (including radiographic, nuclear medicine, DEXA)?***
No

V.14 ***Will any subject be asked to undergo a radiation therapy procedure (including external beam therapy, brachytherapy, or nuclear medicine therapy)?***
No

V.20 ***Does this project involve the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human research participant?***
No

V.21 ***Will any portion of this project be conducted in the CRU, or does it use any CRU resources?***
No

V.22 ***Will this project use any resource/patients of the HCCC?***
No

V.23 ***Will any part of this project be conducted on VAMC premises?***
No

V.24 ***Does this project involve VAMC patients or records?***
No

V.25 **.a** ***Will the study involve <u>any</u> of the following activity at UI Health Care, even if subjects or their insurance will not be billed for the item or service, and regardless of the study funding source (including studies with departmental or no funding)?***

- ***Procedures, tests, examinations, hospitalizations, use of Pathology services, use of clinic facilities or clinical equipment, or any patient care services, including services conducted in the Clinical Research Unit; or***
- ***Physician services or services provided by non-physicians who are credentialed to bill (ARNPs, Physician Assistants, etc.)***

Yes

V.26 ***The study involves nursing, nursing resources or evaluates nursing practices.***
No

VI. Subjects

VI.1 ***How many adult subjects do you expect to consent or enroll for this project?***
50

VI.2 ***What is the age of the youngest adult subject?***
18.0

VI.3 ***What is the age of the oldest adult subject?***
90.0

VI.4 ***What is the percentage of adult male subjects?***
50

VI.5 ***What is the percentage of adult female subjects?***
50

VI.6 ***How many minor subjects do you expect to consent or enroll for this project?***
50

VI.7 ***What is the age of the youngest minor subject?***

0.0

VI.8 ***What is the age of the oldest minor subject?***
17.0

VI.9 ***What is the percentage of minor male subjects?***
50

VI.10 ***What is the percentage of minor female subjects?***
50

VI.11 ***Will any of the minors enrolled be in foster care or Wards of the court?***
No

VI.13 ***Describe EACH of your subject populations***

- ***Include description of any control group(s)***
- ***Specify the Inclusion/Exclusion criteria for EACH group***
- ***Studies under IRB-03 enrolling non veterans as part of the subject population must present a compelling argument to the IRB for the inclusion of non-Veterans (e.g., insufficient number of Veterans; survey of VA employees; study of active duty military; study involving Veterans' family members), and the research is relevant to the care of Veterans or active duty military personnel.***

The study populations will include 50 pediatric patients and 50 adult patients scheduled for cardiothoracic or interventional cardiac surgeries under general anesthesia. We will exclude any patients with known esophageal abnormalities, lesions or disease that would disqualify the patient for the use of TEE as standard procedure. We will also exclude any patients that come to the catheter laboratory exclusively for TEE exam as our study will only occur in patients already scheduled to undergo TEE use in surgery or diagnostic procedure. This will ensure that our study occurs only as a part of standard procedure and will not lengthen time under anesthesia or time in the operating room. There is no control population needed.

VI.14 ***Provide an estimate of the total number of subjects that would be eligible for inclusion in each of your study populations (include your control population if applicable)***
50 pediatric patients and 50 adult patients. There is no control population needed. We expect to complete this study in one year.

VI.15 ***Describe how you will have access to each of your study populations in sufficient number to meet your recruitment goals.***
Outpatient pediatric and adult cardiac surgery patients will be recruited at the cardiology clinics when patients visit for the preoperative evaluation. Inpatient cardiac patients will be identified initially by using the EPIC operating room schedule on the day before surgery. We will have access to these populations by working within the Department of Anesthesiology, and by monitoring the OR schedule for patients scheduled to undergo cardiothoracic or interventional cardiac diagnosis and surgeries. The use of TEE is standard procedure for visualizing the heart in these procedures. A trained TEE operator will be available to control and capture images. Patients will be recruited until data has been collected in 50 pediatric patients and 50 adult patients.

VI.16 ***Do you <u>plan</u> to recruit/enroll non-English speaking people?***
No

VI.18 ***Do you propose to enroll any of the following in this study as subjects?***

- ***Employee of the PI or employee of a research team member***
- ***Individual supervised by PI or supervised by member of research team***
- ***Individual subordinate to the PI or subordinate to any member of the research team***
- ***Student or trainee under the direction of the PI or under the direction of a member of the research team***

No

VI.20 ***Will subjects provide any information about their relatives?***
No

VI.23 ***Will anyone (other than the subject) provide you with information about the subject (e.g. proxy interviews)?***
No

VI.26 ***Is this project <u>about</u> pregnant women?***
No

VI.27 ***Will this project involve fetuses?***
No

VI.28 ***Does this project involve adult subjects who may be incompetent or have limited decision-making capacity on***

initial enrollment into the study?
No

VI.32 ***Does this project involve subjects whose capacity to consent may change over the course of the study?***
No

VI.37 ***Does this project involve prisoners as subjects?***
No

VII.A. Project Description (A)

Where will project procedures take place (check all that apply)?
- UIHC - Main Operating Rooms, Pediatric Catheter Laboratory, Pediatric and Adult Cardiac Surgery Clinics

Is this project also being conducted by other researchers at their own sites (e.g. a multi-site collaborative project)?
No

VII.B. Project Description (B)

VII.B.1 ***Does this project involve any of the following:***

- ***clinical intervention***
- ***pharmacologic intervention***
- ***therapeutic intervention***
- ***physiology studies (e.g. studying the functions of organs, tissues, or cells)***

Yes

VII.B.2 ***Does this project involve a drug washout (asking subject to stop taking any drugs s/he is currently taking)?***
No

VII.B.6 ***Will any subjects receive a placebo in this study when, if they were not participating, they could be receiving an FDA-approved treatment for their condition?***
No

VII.B.11 ***Is there a separate, written protocol that will be submitted in addition to this IRB New Project form? (Note: a grant application is not considered to be a protocol)***
No

VII.B.18 ***Does this project involve testing the safety and/or efficacy of a medical device?***
Yes

VII.B.19 ***Describe in detail procedures in place for maintaining device shipment and receipt records:***
This device is already onsite being used in the UIHC Main Operating Room and Pediatric Catheter Laboratory of alternative purposes, thus, no device shipping or receipt will occur.

VII.B.20 ***Who will be responsible for maintaining these shipment and receipt records?***
N/A

VII.B.21 ***Describe in detail procedures in place for tracking use and disposition of devices described in this study:***
N/A

VII.B.22 ***Who will be responsible for maintaining these use and disposition tracking records?***
N/A

VII.B.23 ***Describe in detail procedures in place to limit access to authorized study personnel for the storage, control, and dispensing of the investigational devices. (For example, investigational devices are kept in a locked area away from approved devices or have a keyed interlock, and only study personnel authorized to dispense the device have the keys)***
N/A

VII.B.24 ***Is the device FDA-approved for the way it will be used in this study?***
No

VII.B.25 ***Is there an IDE (Investigational Device Exemption) for this device in this research project?***
No

VII.B.29 ***Indicate the appropriate FDA status you and/or the sponsor are requesting for the use of this device in this study.***
Non-Significant Risk (NSR) device/software

VII.B.31 ***Provide a detailed rationale for why this device meets the FDA definition of a Non-Significant Risk Device (NSR)***
Because it is not intended as an implant nor is it to be used in supporting or sustaining human life. At this time it is not of substantial importance in diagnosing, curing, mitigating or treating disease.

VII.B.32 ***Provide a summary of prior investigations with this device.***
Transesophageal echocardiography is a semi-invasive, monitoring and analytic tool used to generate reproducible images of the heart and mediastinum. TEE is routinely used in cardiothoracic and interventional surgeries as well as in detecting thromboses, valvular defects and congenital heart disease. There has been expanding utilization of TEE outside of cardiac surgery as a potential haemodynamic monitor both intraoperatively and postoperatively (Pissarra 2012). While TEE is not regularly used to visualize the spinal column, it can be done with relative ease when consciously attempted (Chitilian 2006). To our knowledge, this prospective observational study will be the first attempt to deliberately image the structures within the vertebral foramen, to scan the spinal segments identified by TEE and to classify the TEE image quality by a trained sonographer. Given the nearly universal use of TEE in cardiac surgical operating rooms, in combination with the low risk of complications(Daniel 1991), potential outcomes include the use of TEE in the placement of thoracic epidural catheters, in identification of spinal cord trauma or as a monitor of intraoperative perfusion and pressure surrounding the spinal cord (Godet 1994). This could lead to improved precision, success and safety of regional anesthesia.

VII.B.33 ***Have there been any prior IRB reviews (at UI or elsewhere) and/or determinations made with regard to this device?***
Yes

VII.B.34 ***Provide a discussion of these reviews/determinations.***
Yes, as TEE is a standard intraoperative monitor, multiple studies have demonstrated a low rate of complications associated with TEE, deeming it safe for use in surgery (Daniel 1991).

VII.B.35 ***Has the FDA made an assessment of risk with regard to this device?***
No

VII.B.36 ***Has this device/software been approved by the FDA for another indication or in another form from its use in this project?***
Yes

VII.B.37 ***Describe differences between approved device/software and its use in this study:***
TEE is routinely used in cardiothoracic and interventional surgeries as well as in detecting thromboses, valvular defects and congenital heart disease. In this study, TEE will not be used in a similar manner but to visualize the spinal column as can be done with relative ease when consciously attempted (Chitilian 2006). To our knowledge, this prospective observational study will be the first attempt to deliberately image the structures within the vertebral foramen, to scan the spinal segments identified by TEE and to classify the TEE image quality by a trained sonographer. Given the nearly universal use of TEE in cardiac surgical operating rooms, in combination with the low risk of complications(Daniel 1991). This could lead to improved precision, success and safety of regional anesthesia.

VII.C. Project Description (C)

VII.C.1 ***Does this project involve any research on genes or genetic testing/research?***
No

VII.D. Project Description (D)

VII.D.1 ***Check all materials/methods that will be used in recruiting subjects (you will need to attach copies of all materials at the end of the application):***

- Use of any information available to the researchers or their colleagues because this person is a patient OR use of any information considered to be Protected Health Information (PHI) OR review of patient/clinic records - Operating room schedule
- Referral from colleague - Thoracic surgery physicians and nurses may identify potential patients. Also, some patients may be identified by Pre-Anesthesia Evaluation Clinic staff.

VII.D.2 ***List the individual data elements you will need to access/use from the patient or clinic records to***

identify potential subjects for recruitment
We will need to access patient records to check the patient's eligibility for the study by checking their surgical procedure, past medical history, counter indications for TEE use intra-operatively (esophageal trauma, lesion or disease) and age.

VII.D.3 ***Describe why you could not practicably recruit subjects without access to and use of the information described above***
Many patients may be unaware that they are eligible for the study because they do not understand the routine use of TEE in the operating room. Also, patients coming to UIHC for this type of surgery come from all over Iowa and surrounding states. Recruitment of eligible patients outside of Iowa City for such a specific study population would be extremely difficult.

VII.D.4 ***Describe why you could not practicably obtain authorization from potential subjects to review their patient or clinic records for recruitment purposes.***
We could not practicably obtain authorization from potential subjects to review their patient or clinic records because the population being studied is very specific. We would have to ask all patients who arrive in the thoracic surgery clinic for permission to review their charts in order to identify the possible participants needed.

VII.D.5 ***Describe plans to protect the identifiers from improper use or disclosure***
The only people who will have access to the data collected for this study will be members of the research team. After data collection, the data will be immediately transferred electronically to a password protected file on a password protected computer and paper files will be kept in a locked filing cabinet in a locked office.

VII.D.6 ***Describe plans to destroy identifiers at the earliest opportunity consistent with conduct of the research***
Paper identifiers will be shredded and electronic identifiers will be completely cleared from computers at the earliest opportunity consistent with the conduct of this project.

VII.D.7 ***Does the research team agree that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the study, or for other research for which the use or disclosure of the requested information would be permitted by the HIPAA Privacy Rule***
Yes

VII.D.8 ***Will a member of the research team discuss the study with the subject in person prior to the subject agreeing to participate?***
Yes

VII.D.9 ***Describe the physical location where the consent process will take place:***
In most cases the patients will be approached in the Thoracic Surgery Clinic, Pediatric Intensive Care Unit or Anesthesia Pre-Surgical Evaluation Clinic approximately 24 hours before surgery. Patients approached in the Thoracic Surgery Clinic will recieve a copy of the consent form to take home with them. Those patients who are consented the day of surgery will have 1-5 hours before the surgery begins. Patients will be consented before they receive any sedation.

VII.D.10 ***Will a member of the research team discuss the study with the subject by phone prior to the subject agreeing to participate?***
Yes

VII.D.11 ***Describe:***
If subjects have questions for the research team they are able to contact team members by phone as provided on the consent.

VII.D.12 ***Who will be involved in the consent process (including review of consent document, answering subjects' questions)?***

Name	Consent Process Involvement
Kenichi Ueda, MD	Yes

VII.D.15 ***Check all materials that will be used to obtain/document informed consent:***
- Consent Document

VII.D.16 ***Are you requesting a waiver of documentation of consent (either no subject signature or no written document)?***
No

VII.D.19 ***Before the subject gives consent to participate are there any screening questions that you need to directly ask***

the potential subject to determine eligibility for the study?
Yes

VII.D.20 ***List any screening questions you will directly ask the potential subject to determine eligibility.***
We will ask if the subject has any known esophageal abnormalities, lesions, disease or other issues that would increase risks associated with transesophageal echocardiographic imaging.
We will ask the subject if they are pregnant or incarcerated.

VII.D.21 ***Will you keep a screening log or other record that would include information on people who do not enroll in the study?***
No

VII.D.25 ***<u>After</u> the subject agrees to participate (signs consent), are there any screening procedures, tests, or studies that need to be done to determine if the subject is eligible to continueparticipating?***
No

VII.D.27 ***Discuss how much time a potential subject will have to agree to consider participation and whether or not they will be able to discuss the study with family/friends before deciding on participation.***
Use of TEE is standard in cardiac surgeries. Patients who are approached in the Thoracic Surgery Clinic will have at least 24 hours to agree to consider participation in our study. These patients will recieve a consent form to take home for further discussion. Patients who are approached on the day of surgery will have 1-5 hours to agree to consider participation in the study. All patients will have the opportunity to discuss with family/friends before deciding on participation.

VII.D.28 ***How long after the subject agrees to participate do study procedures begin?***
Patients who are consented in the pre-operative clinic will have at least 24 hours between agreeing to participate and their surgery. Patients who are consented the morning of surgery will have between one and five hours from the time of consent until their surgery. Patients will be consented before they receive any sedation.

VII.D.29 ***Provide a description of the enrollment and consent process for adult subjects***

- ***Describe each study population separately including control population***
- ***Include when recruitment and consent materials are used***
- ***Use 3rd person active voice "The Principal Investigator will identify subjects. For example, the principal investigator will identify potential subjects, the study coordinator will discuss the study with subjects over the telephone and schedule the first study visit, etc..."***
- ***Describe the steps that will be taken by the research team to minimize the possibility of coercion or undue influence during the consent process***

We will identify patients who meet the inclusion criteria by reviewing the pre-operative clinic patient list and operating room schedule. All patients will be consented in the same manner.

In most cases we will approach the patients in the Thoracic Surgery Clinic, Pediatric Intensive Care Clinic or Anesthesia Pre-Surgical Evaluation Clinic at least 24 hours before surgery. We will introduce ourselves as members of the anesthesia team. We will explain the study and standard TEE procedure, including benefits and risks to the the patient and provide them a copy of the consent document. The patients will have the opportunity to ask questions and discuss their participation with family or friends. Patients will also recieve a copy of the consent form to take home with them. Patients who agree to participate will sign the consent document and will be provided with a copy of the consent. The consent document will contain contact information that the patient may use to contact the research team with any questions or concerns.

Those patients who are consented the day of surgery will be approached by a nurse and handed a card which states that the patient is elibible to participate in a research study. If they are interested in participating, a member of the research team will explain the study to the patient. We will explain the study, including benefits and risks, to the the patient and provide them with a copy of the consent document. The patients will have the opportunity to ask questions and discuss their participation with family or friends. Patients who agree to participate will sign the consent document and will be provided with a copy of the consent. The consent document will contain contact information that the patient may use to contact the research team with any questions or concerns. Patients will have between one and five hours after consent is obtained before their surgery. No sedation will be given before the consent is obtained.

Further, in order to minimize the possibility of coercion or undue influence during the consent process, potential subjects will be reminded that participation is voluntary and choosing not participate will not affect their surgery/care when they discuss the consent for with the research team.

VII.D.30 ***Describe how you will obtain the consent of the parents or legal guardians for child/minor subjects in this study***

- ***Describe each study population separately including control population***
- ***Include when recruitment and consent materials are used***
- ***Use FIRST person, and provide detail as to order of events***
- ***Describe the steps that will be taken by the research team to minimize the possibility of coercion or undue influence during the consent process***

For children/minors who are too young to assent or consent on their own:

We will identify patients who meet the inclusion criteria by reviewing the pre-operative clinic patient list and operating room schedule. All patients or their guardians will be consented in the same manner.
In most cases we will approach the patient's guardian in the Thoracic Surgery Clinic, Pediatric Intensive Care Clinic or Anesthesia Pre-Surgical Evaluation Clinic at least 24 hours before surgery. We will introduce ourselves as members of the research study team. We will explain the study, including benefits and risks, to the the patient's guardian and provide them a copy of the consent document. Guardians will have the opportunity to ask questions and discuss the subject's participation with family or friends. Guardians will also receive a copy of the consent form to take home with them. Guardians who agree to patient participation will sign the consent document and will be provided with a copy of the consent. The consent document will contain contact information that the patient or guardian may use to contact the research team with any questions or concerns.
Those patients who are consented the day of surgery will have their guardian approached by a nurse and handed a card which states that the patients is eligible to participate in a research study. If they are interested in participating, a member of the research team will explain the study to the patient. We will explain the study, including benefits and risks, to the the patient and provide them with a copy of the consent document. The guardian will have the opportunity to ask questions and discuss their participation with family or friends. Guardians who agree to patient participation will sign the consent document and will be provided with a copy of the consent. The consent document will contain contact information that the patient may use to contact the research team with any questions or concerns. Patients will have between one and five hours after consent is obtained before their surgery. No sedation will be given before the consent is obtained.

For children/minors who will sign an assent document or are old enough to sign a consent document:
We will identify patients who meet the inclusion criteria by reviewing the pre-operative clinic patient list and operating room schedule. All patients will be consented in the same manner.
In most cases we will approach the patient and their guardian in the Thoracic Surgery Clinic, Pediatric Intensive Care Clinic or Anesthesia Pre-Surgical Evaluation Clinic at least 24 hours before surgery. We will introduce ourselves as members of the research study team. We will explain the study, including benefits and risks, to the the patient and their guardian and provide them a copy of the assent document. The patients will have the opportunity to ask questions and discuss their participation with family or friends. Patients will also receive a copy of the assent form to take home with them. Patients who agree to participate will sign the assent document and will be provided with a copy of the assent. The assent document will contain contact information that the patient may use to contact the research team with any questions or concerns.
Those patients who are assented the day of surgery will be approached by a nurse and handed a card which states that the patients is eligible to participate in a research study. If they are interested in participating, a member of the research team will explain the study to the patient. We will explain the study, including benefits and risks, to the the patient and provide them with a copy of the assent document. The patients will have the opportunity to ask questions and discuss their participation with family or friends. Patients who agree to participate will sign the assent document and will be provided with a copy of the assent form. The assent document will contain contact information that the patient may use to contact the research team with any questions or concerns. Patients will have between one and five hours after consent is obtained before their surgery. No sedation will be given before the assent is obtained.

VII.D.31 ***What are the plans for the assent process for children/minors in this study? (You may choose more than one procedure if you have different child populations in your study)***

- Children/minors will sign an assent or consent document -
- No assent procedure because some or all of the children/minors do not have the capability to assent or their capability is so limited that they cannot reasonably be consulted to provide assent -

VII.D.36 ***Provide a detailed description and rationale for each of the procedures chosen above and describe the child/minor populations to which they apply in your study.***

For those children/minors who are too young (younger than 7 years old) to assent on their own or their capability is so limited they cannot reasonably do so, their parent or guardian will consent on their behalf. All procedures and information will be explained by a member of the research team and all questions will be answered before consent is obtained.
For those children/minors that are old enough to sign an assent (7-12 years old) or consent (>12 years old) document, they will also have all procedures and information explained by a member of the research team and will be given the opportunity to ask questions before assent/consent is obtained.

VII.D.37 ***Does the study include any form of deception (e.g., providing participants with false information, misleading information, or withholding information about certain study procedures)?***

Examples:

- ***Procedure includes a cover story that provides a plausible but inaccurate account of the purposes of the research.***
- ***Participants will be provided with false information regarding the particular behaviors of interest in the research.***
- ***Procedures include a confederate pretending to be another participant in the study.***
- ***Participants will be told that the research includes completion of a particular task, when in fact, that task will not be administered.***
- ***Study is designed to introduce a new procedure (or task) that participants are not initially told about.***
- ***If yes, a waiver of informed consent must be requested under question IV.3.***

No

VII.E. Project Description (E)

VII.E.1 ***Will subjects be randomized?***
No

VII.E.3 ***Will any questionnaires, surveys, or written assessments be used to obtain data directly from subjects in this study?***
No

VII.E.5 ***Does this project involve creating any audiotapes, videotapes, or photographs?***
No

VII.E.6 ***Provide a detailed description in sequential order of the study procedures following the consent process - DO NOT cut and paste from the Consent Document.***

Describe study populations separately if they will be participating in different procedures - include CONTROL population if applicable.

DESCRIBE:

- ***What subjects will be asked to do/what happens in the study (in sequential order)***
- ***The time period over which procedures will occur***
- ***The time commitment for the subject for individual visits/procedures***
- ***Long-term followup and how it occurs***

The subjects of the study, scheduled to undergo cardiothoracic or interventional cardiac surgeries, will only be asked to come to their surgery. The day of surgery the patients will not be required to do anything different from standard anesthesia and surgical practice at the hospital. Subjects will come to the operating room suite and the usual monitors (electrocardiogram, non-invasive blood pressure, and oxygen saturation) will be placed.
Following the routine induction of anesthesia, the Mini-Multi TEE probe (Model T6207 (21381A), Philips, Bothell, WA, USA) will be advanced to mid esophageal level in order to visualize the heart, this is standard surgical procedure in these cases. Rotation of the probe by approximately 180 degrees toward the descending aorta, with an increased gain and depth decreased to 2-3 cm, will attempt to allow for appreciation of the spinal cord and epidural space. Upon confirmation of the structures within the vertebral foramen by a trained TEE operator, an images of the spine will be captured to be later graded as high, medium or low quality by a trained sonographer. The TEE probe will then be advanced caudally and intervertebral disc spaces will be counted in order to determine the number of spinal segments that can be spanned until an image can no longer be generated. This will take approximately ten minutes, but will occur while the patient is being prepared for surgery so no additional time in the operating room will be necessary. At this point, the TEE probe will be returned to mid esophageal level to visualize the heart and the operation will proceed as usual. When looking at patient medical records, we will only collect the following data: height, weight, age, any known history of esophageal abnormalities, lesions or disease and current procedure. Ten minutes is the approximate additional time that may be required intraoperatively to observe the spinal cord on TEE but this will not extend the time in the operating room and thus no additional billing is required. No additional visits or extra time is required of the subject. There will be no necessary long-term follow up or data collection. When the patient leaves the operating room, nothing additional is required.

VII.E.7 ***Will you attempt to recontact subjects who are lost to follow-up?***
No - followup is not required in this study

VII.E.9 ***Will subjects be provided any compensation for participating in this study?***
No

VIII. Risks

VIII.1 ***What are the risks to subjects including***
- emotional or psychological
- financial
- legal or social
- physical?
The care the patient will receive is standard practice at UIHC for thoracic or interventional cardiac surgeries and are necessary procedures regardless of this research study. Thus, no additional physical risk is involved. Patients may be under slightly elevated emotional stress knowing that they are part of a research study. There is a very low risk of loss of confidentiality of the patient's medical information, yet this is unlikely as patients will be given identification numbers at the earliest date possible and these will only be accessed by members of the research team. Only the data necessary to answer the research question will be collected upon reviewing patient information. There are no other known financial, physical or legal risks to the patient.

VIII.2 ***What have you done to minimize the risks?***

- ***If applicable to this study ALSO include:***
  - ***How you (members of your research team at Iowa) will monitor the safety of individual subjects.***
  - ***Include a description of the availability of medical or psychological resources that subjects might require as a consequence of participating in this research and how referral will occur if necessary (e.g. availability of emergency medical care, psychological counseling, etc.)***

Healthcare professionals will monitor the subject at all times during the operation. The patient will be reassured that although they are participating in the study, everything that happens during the case is already standard practice at UIHC for thoracic and cardiac surgery patients. All patients will be given an identification number and be referred to by such. To prevent loss of confidentiality of the patient's medical information, we will keep all records used for this study in a locked office or on password protected computer system. Only members of the research team will have access to the records used in this study. No key will be kept as patients will not need to be contacted in the future.

VIII.3 ***Does this study have a plan to have an individual or committee review combined data from all subjects on a periodic basis (such as summary or aggregate safety and/or efficacy data)?***
No

IX. Benefits

IX.1 ***What are the direct benefits to the subject (do not include compensation or hypothesized results)?***
There are no direct benefits to the subject.

IX.2 ***What are the potential benefits to society in terms of knowledge to be gained as a result of this project?***
This novel confirmation method of visualizing the spinal cord and epidural space could be utilized in the future to detect spinal trauma, vascular events surrounding the spinal cord or detect hematoma. It could also be used in thoracic epidural catheter placement to improve the safety and success rate of epidural analgesia and potentially improve future patient care.

X. Privacy & Confidentiality

X.1 ***What are you doing to protect the privacy interests of the subjects?***
To protect patient privacy, researchers will be conducting the consent and study procedures in a private setting. Further, the research team will only be collecting the information necessary to complete the study.

X.2 ***Are you collecting the Social Security Number of any subjects for any purpose?***
No

X.4 ***How will information/data be collected and stored for this study (check all that apply):***

- Electronic records (computer files, electronic databases, etc.) - Electronic records will be kept on the password protected Anesthesia department server. The members of the research team will be the only people with access to the files. No records will be kept on personal computers. Further, patients will be assigned a unique identification number. They will always be referred to by this number. The patient's hospital number and day of surgery will be recorded, but will not be disclosed to anyone outside the research team. We will record the hospital number only to access the patients' chart later if needed. The database that contains the identifiers will be password protected so that the only the investigators needing it can access it. No unnecessary patient identifiers will be recorded, and those that are needed will be deleted at the earliest possible time. Only data necessary to collect for the study will be recorded.
    - Name - Dave Griffiths
    - Title - System Administrator and System Programmer II
    - University Job Classification - IT Security Officer
- Paper/hard copy records (hard copy surveys, questionnaires, case report forms, pictures, etc.) - Paper/hard copy records, including consent documents and any other material printed for the study, will be stored in the primary invetigator's office in a locked file cabinet. Further, patients will be assigned a unique identification number. They will always be referred to by this number. The patient's hospital number and day of surgery will be recorded, but will not be disclosed to anyone outside the research team. We will record the hospital number only to access the patients' chart later if needed. The database that contains the identifiers will be password protected so that the only the investigators needing it can access it. No unnecessary patient identifiers will be recorded, and those that are needed will be deleted at the earliest possible time. Only data necessary to collect for the study will be recorded.

X.5 ***Do the confidentiality protections indicated above allow only members of the research team to access the data/specimens?***
Yes

XI. Data Analysis

XI.1 ***Describe the analysis methods you will use, including, if applicable, the variables you will analyze***
We are not planning to compare pediatric vs adult rates, we just want to observe the ability to image the spinal cord using TEE in this observational study. Thus, we will only use exploratory descriptive statistics for analysis.

XI.2 ***Provide the rationale or power analysis to support the number of subjects proposed to complete this study.***
Because this is a novel technique, we have no base for the ability to visualize the spinal cord via TEE. We assume that fifty pediatric patients and fifty adult patients will provide adequate power to confirm that the spinal cord can adequately be observed on TEE image.

XII. Future Research

XII.1 ***Do you wish to keep any information about subjects involved with this research project so that members of the current research team may contact them in the future for your own research projects?***
No

XII.2 ***Do you wish to keep any information about subjects involved with this research project so that other researchers may contact them for future research?***
No

XII.4 ***Does this project involve storing any data, tissues or specimens for future research?***
Yes – contribution for future use is mandatory for participation in the study

New Project Form Attachments

Attachment Name	Category	Ver	Size	Attached
Assent_Ueda.rtf	Consent & Assent Forms	3	47 k E	07/19/12
Recordofconsent_Final.rtf	Consent & Assent Forms	2	57 k E	06/21/12
Ueda_Prospectiveconsent_Final722012.rtf	Consent & Assent Forms	4	171 k E	07/19/12
Ueda reviewer questions.pdf	Miscellaneous	1	71 k E	07/13/12
AssuranceUedaTEE18Jun12.pdf	Assurance Document	1	74 k E	06/18/12