Informed Consent Form

Protocol Title: Utilization of Confocal Microscopy During Cardiac Surgery

Document Date: October 19, 2018

IRB Approval Date: October 31, 2018

NCT Number: NCT03189134

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Principal Investigator: Aditya K. Kaza, MD

Why is this research study being conducted? What is its purpose?

The research study is being done to establish the effectiveness of using a specific type of microscope and a special dye called fluorescein for identifying different tissue types in the heart during heart surgery. The purpose of this project is to develop a new system to avoid injury to the electrical pathways in the heart. These electrical pathways are what help the heart beat with the right rhythm. Any injury to these pathways could require placement of a permanent pacemaker (a device to help the heart beat in the right rhythm).

Fluorescein is approved by the Food and Drug Administration (FDA) for use in eye imaging and angiography. In this study, the use of fluorescein is investigational. This means that the drug has not yet been approved by the FDA for the purpose we are studying, imaging during cardiac surgery.

The microscope we are using in this study, the Cellvizio Imaging System, is cleared by the Food and Drug Administration (FDA) for use during endoscopy. In this study, the use of the Cellvizio Imaging System is investigational. This means the device has not yet been approved by the FDA for the purpose we are studying, imaging during cardiac surgery.

Who is conducting this research study, and where is it being conducted?

The Principal Investigator, Dr. Aditya Kaza, is a cardiac surgeon at Boston Children's Hospital. The study will be conducted at Boston Children's Hospital, and is funded by the National Heart, Lung, and Blood Institutes (NHLBI).

How are individuals selected for this research study? How many will participate?

Any subject who is scheduled for isolated atrial septal defect closure is eligible to participate in the study. We will enroll a total of six subjects for this study.

What do I have to do if I am in this research study?

If you choose to participate or have your child participate in the study, we will use a microscope during your/your child's heart surgery to help determine its usefulness in identifying tissue which makes the heart beat. This microscope is used with a special dye (fluorescein) which will shine when a bright light (laser) from the microscope hits the tissue. While the laser is shining on the heart tissue, pictures will be taken with the microscope. This will only add about three minutes to surgery time. The information obtained from the study will be used to develop a microscope system to assist during heart surgery.

There will be no other tests required of you or your child, specifically for research. We would also like to look through your/your child's medical record and collect existing information about tests you/your child has done clinically.

If you choose not to participate in the study, you/your child will receive his/her routine care and no further action will be needed.

What are the risks of this research study? What could go wrong?

We will discuss the three different potential risks related to the device, laser energy, and the fluorescent dye utilized.

The microscope system has been FDA cleared for imaging of the intestines and lungs. We will use it to image the tissue inside the heart and do not expect any additional risks. There is a small risk of prolonging the procedure because of the imaging process; this additional time will be less than three minutes.

The laser used for the project has been approved by the FDA for use in human beings to help identify various body tissues including the intestines, bladder, and lungs. Using the established safety guidelines, the laser strength generated by this device is 80% less than the approved exposure. Other organ systems will not be exposed to the laser source.

The dye which will be used for this study is FDA approved, but the way we are using it in this study is not FDA approved. Fluorescein sodium (dye) will be diluted and only a small amount of the diluted dye will be used. A small amount of the diluted dye will be applied to the surface of the heart as needed for imaging. There is a possibility of an allergic reaction to the dye, however this chance is very low because we are not administering this dye directly into your/your child's bloodstream; instead we are using it locally on the surface of the heart. Once the imaging is completed, the remaining dye will be rinsed and suctioned from the heart surface. In the rare chance that an allergic reaction occurs, this would be treated by flushing the area with fluids immediately.

What are the benefits of this research study?

There are no immediate benefits to you or your child. However, the study may help us better understand the ability of the imaging system to help identify different types of heart tissue, especially the electrical pathways during open heart surgery. If we can develop a way of identifying tissue during heart surgery, we can reduce the risk of injuring the electrical pathways and ultimately reducing pacemaker placement for future patients undergoing heart surgery.

Are there costs associated with this research study? Will I receive any payments?

There are no extra costs to you. You will not receive any payments related to the study.

We will offer you the care needed to treat any injury that directly results from taking part in this research. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form. If you think you have been injured or have experienced a medical problem as a result of taking part in this research,

tell the person in charge of the research as soon as possible. The researcher's name and phone number are listed in this consent form.

If you go to the Emergency Room or to another hospital or doctor it is important that you tell them that you are in this research. If possible, you should give them a copy of this consent form.

If I do not want to take part in this research study, what are the other choices?

You may choose not to participate. The decision whether or not you wish to participate in this study will not affect your or your child's relationship or care received at Boston Children's Hospital. There are no alternate studies related to intraoperative microscope imaging currently available for your child to participate in.

What are my rights as a research participant?

Participation in the study is completely voluntary and refusal to participate or withdraw from the study will not affect the medical care you receive at Boston Children's Hospital. If you choose to participate in the study, a summary of the research findings will be provided to you at the completion of the research project.

Why would I be taken off the study early?

The research investigator may take you out of this study at any time. This would happen if:

- The study is cancelled by the sponsor.
- Withdrawal of parent/legal guardian permission.

Other information that may help you

Boston Children's Hospital has recently developed a web-based, interactive educational program for parents called "A Parent's Guide to Medical Research." To find out more about research at Children's Hospital, please visit the program at www.researchchildren.org.

Boston Children's Hospital is interested in hearing your comments, answering your questions and responding to any concerns regarding clinical research at Children's Hospital. If you would like further information about the type of clinical research performed at the hospital or have suggestions, questions or concerns regarding clinical research you may send an email to cci@childrens.harvard.edu or call 617 355-7052 between the hours of 8:30and 5:00.

Who may see, use or share your health information?

A copy of this consent form will be placed in your child's medical record.

The results of the tests performed for research purposes will not be placed in your child's medical record. In this manner it will be unlikely that others within the hospital, an insurance company or employer would ever learn of such results.

You/your child's health information is protected by a law called the Health Information Portability and Accountability act (HIPAA). In general, anyone who is involved in this research including those funding and regulating the study may see the data, including information about you. For example, the following people might see information about you:

- Research staff at Boston Children's Hospital involved in this study.
- Medical staff at Boston Children's Hospital directly involved in your care that is related to the research or arises from it.
- Other researchers and centers that are a part of this study, including people who oversee research at that hospital.
- People at Boston Children's Hospital who oversee, advise, and evaluate research and care. This includes the ethics board and quality improvement program.
- People from agencies and organizations that provide accreditation and oversight of research.
- People that oversee the study information such as data safety monitoring boards, clinical research organizations, data coordinating centers, and others.
- Sponsors or others who fund the research, including the government or private sponsors.
- Companies that manufacture drugs or devices used in this research.
- Federal and state agencies that oversee or review research information, such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities.
- People or groups that are hired to provide services related to this research or research at Boston Children's Hospital, including services providers, such as laboratories, and others.
- Your health insurer for portions of the research and related care that are considered billable.

If some law or court requires us to share the information, we would have to follow that law or final ruling.

Some people or groups who get your health information might not have to follow the same privacy rules. Once your information is shared outside of Boston Children's Hospital, we cannot promise that it will remain private. If you/your child decide to share private information with anyone not involved in the study, the federal law designed to protect privacy may no longer apply to this information. Other laws may or may not protect sharing of private health information. If you have a question about this you may contact the Boston Children's Hospital Privacy Office at 857-218-4680 which is set up to help you understand privacy and confidentiality.

Because research is ongoing we cannot give you an exact time when we will destroy this information. Researchers continue to use data for many years so it is not possible to know when they will be done.

We will also create a code for the research information we collect about you so identifying information will not remain with the data and will be kept separately. The results of this research may be published in a medical book or journal or be used for teaching purposes. However your name or identifying information will not be used without your specific permission.

Your privacy rights

If you or your child do not want to participate in this study, you do not have to. If you do want to participate, however, you must sign this form.

If you do not sign this form, it will not affect your care or your child's care at Boston Children's Hospital now or in the future and there will be no penalty or loss of benefits. You/your child can withdraw from the study and end your permission for Boston Children's Hospital to use or share the protected information that was collected as part of the research; however you cannot get back information that was already shared with others. Once you remove your permission, no more private health information will be collected. If you wish to withdraw your health information will need to do so in writing.

You/your child may have the right to get some the information that was shared with others for research, treatment or payment. This information is available after the study analysis is done. To request the information, please contact the Hospital's Privacy Officer at 857-218-4680.

The National Institutes of Health has issued a Certificate of Confidentiality for this research. This adds special protection for the research information and specimens that may identify you. The researchers may not disclose information that may identify you, even under a court order or subpoena unless you give permission. However, a Certificate of Confidentiality does not prevent researchers from disclosing information about you if required by law (such as to report child abuse, communicable diseases or harm to self or others); if you have consented to the disclosure (such as for your medical treatment); or if it is used for other research as allowed by law. In addition the Certificate cannot be used to refuse a request if a governmental agency sponsoring the project wants to audit the research. Any research information that is placed in your medical record would not be covered under this Certificate. The Certificate will not be used to prevent disclosure for any purpose you have consented to in this informed consent document. The Certificate does not stop you from voluntarily releasing information about yourself or your involvement in this research. If others obtain your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Contact Information

I understand that I may use the following contact information to reach the appropriate person/office to address any questions or concerns I may have about this study. I know:

I can call…	At	If I have questions or concerns about
Investigator: **Aditya K. Kaza, MD**	Phone: **617-355-7932** Pager: 617-355-7243 **9183**	▪ General questions about the study ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints
Research Nurse **Breanna Piekarski, RN, BSN**	Phone: **617-919-4457** Pager: 617-560-4694 **7200**	▪ General questions about the study ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints
Office of Clinical Investigations	Phone: **617-355-7052**	▪ Rights of a research subject ▪ Use of protected health information. ▪ Compensation in event of research-related injury ▪ Any research-related concerns or complaints.

- If investigator/study contact cannot be reached.
- If I want to speak with someone other than the Investigator, Study Contact or research staff.

Documentation of Informed Consent and Authorization

- I have read this consent form and was given enough time to consider the decision to participate in this study.
- This research study has been satisfactorily explained to me, including possible risks and benefits.
- All my questions were satisfactorily answered.
- I understand that participation in this research study is voluntary and that I can withdraw at any time.
- I am signing this consent form prior to participation in any research activities.
- I give permission for my/my child's participation in this research study and for the use of associated protected health information as described above (HIPAA).

Parent/Legal Guardian Permission (if applicable)

If the child to be involved in this research study is a foster child *or a* ward of the state *please notify the researcher or their staff who is obtaining your consent.*

■ _____ _____ _____
Date (MM/DD/YEAR) Signature of **Parent #1** or **Legal Guardian** Relationship to child

■ _____ _____ _____
Date (MM/DD/YEAR) Signature of **Parent #2** Relationship to child

☐ CHECK if 2nd parent signature **not** obtained above. The PI must document in research records, the reason and/or all attempts made before concluding 2nd parent was not '*reasonably available'*.

Child Assent (if applicable)

■ _____ _____
Date (MM/DD/YEAR) Signature of **Child/Adolescent Subject**

■ If child/adolescent's assent is **not** obtained above, please indicate reason below (check one):

☐ Assent is documented on a separate IRB-approved assent form
☐ Child is too young
☐ Other reason (e.g. sedated), please specify: _____

Adult Participant (if applicable)

■ _____ _____

Date (MM/DD/YEAR) Signature of **Adult Participant (***18+ years)*

Investigator or Associate's Statement & Signature

- I have fully explained the research study described above, including the possible risks and benefits, to all involved parties (subject/parents/legal guardian as applicable).
- I have answered and will answer all questions to the best of my ability.
- I will inform all involved parties of any changes (if applicable) to the research procedures or the risks and benefits during or after the course of the study.
- I have provided a copy of the consent form sign by the subject/ parent / guardian and a copy of the hospital's privacy notification (if requested)

■ _____ _____

Date (MM/DD/YEAR) Signature of **Investigator or Associate**

Witness Statement & Signature

A witness must be present for the entire consent process in the following situations (please check the appropriate box)

☐ The individual cannot read and this consent document was read to the participant or legal representative, **or**

☐ The individual has certain communication impairments that limit the participant's ability to clearly express consent **or**

☐ Situations where the IRB requests a witness be present: please specify _____

I confirm that the information in this consent form was accurately explained to the participant, parent or legally authorized representative, the individual appeared to understand the information and had the opportunity to ask questions, and that informed consent was given freely.

☐ _____ _____

Date (MM/DD/YEAR) Signature of Witness