Study Title: Nasal vs. Oral Intubation for Neonates Requiring Cardiac Surgery

University of Virginia IRB for Health Sciences Research Protocol #20789

Principle Investigator: Melissa Yildirim, MD

Document Type: Informed Consent
Document Date: 4/28/20

Parents' or Guardians' Permission for Your Child to Be in a Research Study

In this form "you" means the child in the study *and* the parent or guardian. If you are the parent or guardian, you are being asked to give permission for your child to be in this study.

In this form "we" means the researchers and staff involved in running this study at the University of Virginia.

Participant's Name_____

Principal Investigator:	Melissa Yildirim, MD University of Virginia Health System PO Box 800725 Charlottesville, VA 22908-0136 Telephone: (434) 924-0000, pager number 4842

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a signed copy of this form.

Why is this research being done?

All babies who need heart surgery have a breathing tube placed by an anesthesiologist. While the baby has a breathing tube in place, they cannot eat by mouth and will be fed by a tube into their stomach. Sometimes after the breathing tube is removed, babies have a hard time learning how to eat by mouth. This may keep them in the hospital for a longer time, or they may need a feeding tube in order to go home.

The purpose of this study is to see if babies eat better after surgery if their breathing tube for surgery is placed in their mouth or in their nose. Babies who eat better may be able to go home from the hospital sooner. Babies who eat better may not require a feeding tube in order to go home.

You are being asked to be in this study, because your baby needs heart surgery in the first two weeks of life.

Up to 88 people will be in this study at UVA.

How long will this study take?

Your baby will be in this study from the time you consent until about one month after he/she is released from the hospital. Your participation in this study will not require extra time. Every baby gets a breathing tube for heart surgery. The only difference is the location of the breathing tube (in the mouth or nose).

What will happen if you are in the study?

SCREENING (visit will last about 15 minutes)

If you agree to participate, you will sign this consent form before any study related procedures take place. Before you can start in the study, we will check your baby's medical records to make sure this study is a good fit for your baby.

If the medical records show that your baby is eligible to be in the study, the study will begin on the day of heart surgery.

STUDY TREATMENT

You will be randomly assigned (like the flip of a coin) to 1 of 2 study treatment groups. You have an equal chance of being assigned to any one of the groups. Neither you nor your doctor can choose which treatment you are assigned.

GROUP 1: Breathing tube in mouth **GROUP 2:** Breathing tube in nose

All babies have a breathing tube placed for heart surgery. If your baby is assigned to Group 1, the breathing tube will be placed in the mouth. If your baby is assigned to Group 2, the breathing tube will be placed in the nose. Placing the breathing tube in the nose may take slightly longer than placing the breathing tube in the mouth. Sometimes it is not possible to place a breathing tube through the nose, and it will be placed in the mouth instead. Both of these procedures are routinely used for babies having heart surgery. The anesthesiologist who places the breathing tube has experience in both procedures.

After surgery, the pediatric intensive care doctors will determine when it is safe to remove the breathing tube, just as they would if you were not in this study. The pediatric intensive care doctors and cardiologists will determine your baby's feeding plan. The study team will not determine when and how your baby is fed after surgery.

We will collect information from your baby's medical record before, during, and after he/she has heart surgery, until he/she is discharged from the hospital, and up to 30 days after his/her discharge. The information we will collect from his/her medical record includes: details about heart surgery, medicines used after surgery, and how your baby learns how to eat.

What are your responsibilities in the study?

As the parent/legal guardian of a baby in this study, you have certain responsibilities to help ensure your baby's safety.

These responsibilities are listed below:

- You must be completely truthful about your child's health history.
- Follow all instructions given.

What are the risks of being in this study?

There are risks to being randomized to either group. Please see below:

Risks related to Group 1 (breathing tube in mouth) are rare and include:

- Mouth ulcers
- Groove in the roof of the mouth
- Damage to tooth buds

Risks related to Group 2 (breathing tube in nose) are rare and include:

- Difficulty placing breathing tube and need for a breathing tube in the mouth
- Discovering a problem with the structures of the nose
- Nose ulcers
- Damage to tooth buds

There is a risk of loss of confidentiality, meaning that private health information could be shared by accident.

Other unexpected risks:

You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?

You are not expected to receive any benefit from participating in this study. However, information researchers get from this study may help other babies getting heart surgery in the future.

What are your other choices if you do not join this study?

You do not have to be in this study to be treated for your illness or condition. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include:

- Breathing tube placed in the nose or mouth – this is typically determined by the anesthesiologist's preference.

If you are an employee of UVa your job will not be affected if you decide not to participate in this study.
If you are a student at UVa, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

You will not get any money for being in this study.

Will being in this study cost you any money?

Being in this study will not cost you any money. Breathing tube placement is a normal part of heart surgery and is included in the cost of this hospitalization whether you are in the study or not.

You and/or your insurance company must pay for any tests or care given beyond what is required in this study. In addition, you and/or your health insurance may also have to pay for other drugs or treatments that are given to help you control any side effects. You will have to pay for any costs not covered by your health plan. You may be responsible for any co-payments or deductibles. You may wish to ask your insurance company for an estimate of what these costs might be or if pre-approval is required.

What if you are hurt in this study?

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader can take your baby out of the study. Some of the reasons for doing so may include

a) Your study physician is concerned about your health
b) Your disease gets worse
c) The side effects of the treatment are too dangerous for you
d) New information shows the treatment will not work or is not safe for you

How will your personal information be shared?

The UVa researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address and date of birth
- Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- The people or groups hired to help perform or review this research
- Insurance companies or other organizations that may need the information in order to pay your medical bills or other costs of your participation in the study
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites conducting the same study, and government agencies that provide oversight
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form or complete the "Leaving the Study Early" part of this form and return it to the researchers. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

A copy of this consent form will be put in your medical record. (This is not the same as the record of this research study.) This means that everyone who is allowed to see your medical records will be able to find out that you are in this study. This is done so your regular doctors will know what you receive as part of this study. If you have other health problems during the study, they will be able to treat you properly.

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Melissa Yildirim, MD
University of Virginia Health System
PO Box 800725
Charlottesville, VA 22908-0136 Telephone: 434-924-0000, pager number 4842

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908 Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Parental/ Guardian Permission

By signing below you confirm you have the legal authority to sign for this child.

_____	_____	_____
PARENT/GUARDIAN (SIGNATURE)	PARENT/GUARDIAN (PRINT NAME)	DATE

If an interpreter is involved in the consent process because the parent/guardian does not speak English well or at all, the parent/guardian should NOT sign on the line(s) above – leave the line(s) above blank. Instead, the parent/guardian should sign the Short Form written in the language they can understand.

Interpreter

By signing below you confirm that the study has been fully explained to the potential subject in a language they understand and have answered all their questions.

_____	_____	_____
INTERPRETER (SIGNATURE)	INTERPRETER (PRINT)	DATE

Consent From Impartial Witness

If this consent form is read to the parent(s) because the parent(s) is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The parent may place an X on the Parent Signature line above.

I agree the information in this informed consent form was presented orally in my presence to the parent(s) guardian(s) and the parent(s)/guardian(s) had the opportunity to ask any questions he/she had about the

study. I also agree that the parent(s)/guardian(s) freely gave their informed consent for their child to participate in this trial.

_____	_____	_____
IMPARTIAL WITNESS (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE

Person Obtaining Parental/Guardian Permission

By signing below you confirm that you have fully explained this study to the parent/guardian, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING PARENTAL/ GUARDIAN PERMISSION (SIGNATURE)	PERSON OBTAINING PARENTAL/GUARDIAN PERMISSION (PRINT NAME)	DATE

Notification of My Health Care Provider

Your health care provider will be notified of your participation in this study.

Leaving the Study Early

If you leave the study early the study leader will keep the data collected about you up until the time you leave the study to help determine the results of the study.

Check one option below:

____ I am withdrawing my consent from the intervention or treatment part of this study but agree to continue to have follow up information about me collected by the study team.
The follow up information will be collected by obtaining information from my medical records

____ I am withdrawing my consent for this study. No additional information may be collected about me including follow up information from my medical records.

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Parental/ Guardian Permission

By signing below you confirm you have the legal authority to sign for this child.

_____	_____	_____
PARENT/GUARDIAN (SIGNATURE)	PARENT/GUARDIAN (PRINT NAME)	DATE

Interpreter

By signing below you confirm that the study withdrawal section has been fully explained to the subject's parent/guarding in a language they understand and have answered all their questions.

_____	_____	_____
INTERPRETER (SIGNATURE)	INTERPRETER (PRINT)	DATE