The Children's Hospital of Philadelphia®

Informed Consent Form and HIPAA Authorization

Study Title: **The Videolaryngoscopy in Small Infants (VISI) Trial**

Version Date: February 26, 2018

Principal Investigator: John Fiadjoe, MD Telephone: (718) 753-1177

Your child may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to let your child take part in this study if you do not want to. If you do, your child can leave the study at any time.

In the sections that follow, the word "we" means the study doctor and other research staff.

Why are you being asked to take part in this study?

Your child is being asked to take part in this research study because your child is having a surgery that will require intubation, which is the placement of a breathing tube for anesthesia.

What is the purpose of this research study?

The purpose of this research study is to compare two clinical standard tools, direct laryngoscopy (DL) and video laryngoscopy (VL), which are used to place a breathing tube into a patient's windpipe to allow a patient to breathe during the surgery.

DL allows the doctor to look directly into the patient's throat to the windpipe. VL would show the pictures of the windpipe on a screen. We do not know if either of the tools are better, which is why we are doing this study. We do know that VL may work better but may take slightly longer. This study will help decide if one is better than the other.

Both DL and VL are approved by the U.S Food and Drug Administration (FDA). These are used routinely at The Children's Hospital of Philadelphia (CHOP).

How many people will take part?

Approximately 650 infants will take part in this study internationally, including up to 250 infants at CHOP.

What is involved in the study?

How long will your child be in the study?

If you agree for your child to take part, the participation will last during the intubation process and for one day after surgery.

What are the study procedures?

Randomization: Your child will be randomly assigned into one of two study groups, either the DL or VL group. There is an equal chance of being in either group, just like flipping a coin. The doctor would normally have chosen which device to use. Because your child is in the research study, the doctor will not choose which device will be used.

Medical Record Review: We will review your child's medical records throughout the study to collect baseline medical information and detailed anesthesia information. After surgery, we will collect information about any complications related to intubation. We will also collect information related to your care, such as information from physical exams, heart rate, blood pressure, etc.

Research Data Collection: During the anesthesia, study staff will stay with your child in the operating room to monitor and also record all intubation related activities.

What are the risks of this study?

The risks of this study are minimal. Depending on which device your child is assigned to, intubation may take longer or there may be more attempts to place the breathing tube in the windpipe. Also, being randomized to a specific device takes the choice away from the doctor as to the device they will use. Even though both devices are approved and are routinely used at CHOP, the child might be exposed to device their doctor may not have used.

Risk of breach of confidentiality

As with any study involving collection of data, there is the possibility of breach confidentiality. Every precaution will be taken to secure your child's personal information to ensure confidentiality.

Are there any benefits to taking part in this study?

Your child may be assigned to a device that their doctor may not have used if they were not in this study. Your child may benefit if they are assigned to a device that turns out to be better. However, we cannot guarantee or promise any direct benefit by participating in this study. The knowledge gained from this study may benefit other patients like your child in the future by helping determine optimal intubation methods.

Do you need to give your consent in order to participate?

If you decide to let your child participate in this study, you must sign this form. A copy will be given to you to keep as a record.

What happens if you decide not to let your child take part in this study?

Participation in this study is voluntary. You do not have to take part in order to receive care at CHOP.

If you decide not to take part or change your mind later, there will be no penalties or loss of any benefits to which your child is otherwise entitled.

Can you stop your child's participation in the study early?

You can stop your child being in the study at any time. You do not have to give a reason.

Can the study doctor take your child out of the study early?

The study doctor may take your child out of the study if there is a reason. Some of the reasons the doctor may take your child out of the study include:

- The study is stopped
- New information suggests taking part in the study may not be in your child's best interests.
- The surgery is canceled

What choices does your child have other than this study?

Standard regular intubation is available if you choose to not let your child to participate in this study. You may discuss other options available to you with your child's doctor.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about your child will be collected. This will include information from medical records, procedures, and tests that are part of this research. Information related to your child's medical care at CHOP will go in his/her medical record. This could include physical exams or tests done in the clinical lab. Medical records are available to CHOP staff. Staff will view your child's records only when required as part of their job. Staff are required to keep your child's information private. Information that could identify your child will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. We will do our best to keep your child's personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your child's personal information may be disclosed if required by law.

The results of this study may be shown at meetings or published in journals to inform other doctors and health professionals. We will keep your child's identity private in any publication or presentation about the study.

Several people and organizations may review or receive your child's identifiable information. They will need this information to conduct this research, assure the quality of the data, or to analyze the data. These groups include:

- Representatives of Anesthesia Patient Safety Foundation (APSF) who is the study sponsor funding this research;
- Members of the research team and other authorized staff at CHOP;
- People who help to conduct data analysis;
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.

By law, CHOP is required to protect your child's health information. The research staff will only allow access to your child's health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your child's health information for this research. Some of the organizations listed above may not be required to protect your child's information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your child's health information at any time. To take back your permission, it is preferred that you tell the investigator in writing.

Dr. John Fiadjoe
The Children's Hospital of Philadelphia
34th Street and Civic Center Blvd.
Philadelphia, PA 19104

In the letter, state that you changed your mind and do not want any more of your child's health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your child's personal health information, your child will be withdrawn from the study.

Financial Information

While your child is in this study, the cost of your child's usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your child's insurance.

Will there be any costs to you?

Neither you nor your child's insurance company will be charged for your child's participation in this study.

Will you be paid for taking part in this study?

You or your child will not receive any payments for taking part in this study.

Who is funding this research study?

Anesthesia Patient Safety Foundation (APSF) is funding this research.

What if you have questions about the study?

If you have questions about the study, call the study doctor, Dr. John Fiadjoe at (718)753-1177. You may also talk to your child's own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes

sure your rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to your child's participation. You are also agreeing to let CHOP use and share your child's health information as explained above. If you don't agree to the collection, use and sharing of your child's health information, your child cannot participate in this study. **NOTE:** *A foster parent is not legally authorized to consent for a foster child's participation.*

Name of Subject	
Name of Authorized Representative	Relation to subject: ☐ Parent ☐ Legal Guardian
Signature of Authorized Representative	Date