INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

Conventional Direct Laryngoscopy Vs. Video Laryngoscopy With The C-MAC For Pyloromyotomy

You and your infant are invited to participate in a research study that compares two ways to place a breathing tube. A breathing tube is required for pyloric stenosis surgery. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

The study is being conducted by Dr. Nicole Horn and the anesthesia department at Riley Hospital for Children.

STUDY PURPOSE

The purpose of this study is to compare two different ways of placing the breathing tube. Both ways are used currently to place breathing tubes and are safe and effective. We want to see if one way is better than the other for infants with pyloric stenosis.

NUMBER OF PEOPLE TAKING PART IN THE STUDY:

If you agree to participate, your infant will be one of 72 subjects who will be participating in this research.

PROCEDURES FOR THE STUDY:

If you agree to allow your child to be in the study, the following things will occur:

Your infant will be randomized (like flipping a coin) to one of two groups. One group of infants will have their breathing tubes placed with the standard laryngoscope. The other group of infants will have their breathing tubes placed with a video laryngoscope. The video laryngoscope allows the attending anesthesiologist to see exactly what the resident in training sees when they place the breathing tube. Your infant's participation in the study will last until he or she is discharge from the recovery room. For the study, data regarding the breathing tube placement and your child's oxygen status will be collected.

RISKS OF TAKING PART IN THE STUDY:

While on the study, the risks associated with placing a breathing tube are:

Common: cough, sore throat, need for additional oxygen.
Uncommon: croup (a swelling of the airway, causing a bark like cough that requires a breathing treatment), or vocal cord injury.

BENEFITS OF TAKING PART IN THE STUDY:

There is no direct benefit anticipated. The course of the anesthetic and placement of the airway will be no different than if you were not part of the study. We are asking for consent to randomly place your child in one of two groups and collect data on the process of placing the airway.

ALTERNATIVES TO TAKING PART IN THE STUDY:

Instead of being in the study, you may choose not to enroll your child in the study and the attending anesthesiologist will decide which type of method to use to place your child's airway and no data will be collected for the study.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published and databases in which results may be stored.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP).

COSTS

There are no additional costs to being in this study. The procedures for this study are all standard of care and covered by most insurance policies. If you do not have insurance these cost will be your responsibility.

PAYMENT

You will not receive payment for taking part in this study.

COMPENSATION FOR INJURY

In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled. If you are participating in research which is not conducted at a medical facility, you will be responsible for seeking medical care and for the expenses associated with any care received.

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study or a research-related injury, please call 317-944-9981 and ask for the research coordinator for this study. If you cannot reach the researcher during regular business hours (i.e. 8:00AM-5:00PM), please call the IU Human Subjects Office at (317) 278-3458 or (800) 696-2949. After business hours, please call (317) 312-2871, the on call overnight anesthesia staff.

In the event of an emergency, you may contact Dr. Nicole Horn at (317) 312-1968.

For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, contact the IU Human Subjects Office at (317) 278-3458 or (800) 696-2949.

VOLUNTARY NATURE OF STUDY

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with Riley Hospital for Children at IU Health.

PARENT'S CONSENT

In consideration of all of the above, I give my consent for my child to participate in this research study.

I will be given a copy of this informed consent document to keep for my records. I agree for my child to take part in this study.

Parent's Printed Name:_____

Parent's Signature:_____ **Date:**_____
(must be dated by the parent)

Parent's Printed Name:_____

Parent's Signature:_____ **Date:**_____
(must be dated by the parent)

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____ **Date:**_____

INDIANA UNIVERSITY
AUTHORIZATION FOR THE RELEASE OF MINOR'S HEALTH INFORMATION FOR RESEARCH

Introduction: As the parent and/or legal guardian of _____ (the "Child"), you have the right to decide who may review or use the Child's Protected Health Information ("PHI"). The type of information that may be used is described below. When you consider allowing the Child to take part in a research study, you must give permission as the parent and/or legal guardian to allow the Child's PHI to be released from the Child's doctors, clinics, and hospitals to the research team, for the specific purpose of this research study.

What does this authorization relate to? This authorization relates to the following study:

Conventional Direct Laryngoscopy Vs. Video Laryngoscopy With The C-MAC For Pyloromyotomy

Dr. Nicole Horn	**1306011553**
PRINCIPAL INVESTIGATOR(in charge of Research Team)	*IRB PROTOCOL #* **N/A**
	SPONSOR #
NAME OF CHILD - RESEARCH PARTICIPANT	*BIRTHDATE*
STREET ADDRESS	*CITY, STATE & ZIP CODE*

What information will be used for research purposes? The PHI that will be used for research purposes may include some or all of the Child's health records. This includes, but is not limited to: information provided by you or the Child directly to the Research Team, hospital records and reports; admission histories, and physicals; X-ray films and reports; operative reports; laboratory reports; treatment and test results; immunizations; allergy reports; prescriptions; consultations; clinic notes; and any other medical or dental records needed by the Research Team.

Specific Authorizations: I understand that this release also pertains to the Child's records concerning hospitalization or treatment that may include the categories listed below. I have the right to specifically request that the Child's records NOT be released from his/her health care providers to the Research Team. However, I understand that if I limit access to any of the Child's records listed below, the Child may not be able to be in this research study. Check limitations, if any, below:

- ☐ Mental health records
- ☐ Psychotherapy Notes
- ☐ HIV (AIDS)
- ☐ Sexually transmitted diseases
- ☐ Alcohol / Substance abuse
- ☐ Other: _____

Who will be allowed to release this information?

I authorize the following persons, groups or organizations to disclose the Child's information described in this Release of Information/Authorization for the above referenced research study:

- ☒ **Treating providers**
- ☒ **Hospitals, clinics or other places where I have received treatment**
- ☐ **Other:** _____
- ☒ **The Principal Investigator and the Research Staff**

Who can access your PHI for the study? The people and entities listed above may share the Child's PHI with the following persons or groups for the research study: the Research Team, IU Institutional Review Board and its designees, Research Sponsor and its representatives, Research Organizations, the Department of Health & Human Services or other US or foreign government agencies as required by law, and to the Food and Drug Administration (FDA) or a person subject to the jurisdiction of the FDA in order to audit or monitor the quality, safety or effectiveness of the product or activity.

INDIANA UNIVERSITY
AUTHORIZATION FOR THE RELEASE OF MINOR'S HEALTH INFORMATION FOR RESEARCH

The **Research Team** includes the Principal Investigator, his/her staff, research coordinators, research technicians and other staff members who provide assistance to the Research Team. If there is a **Research Sponsor(s),** this shall include: NA and any **Research Organizations** who provided assistance to the **Research Sponsor(s)** including, but not limited to: NA.

Expiration date of this Authorization: This authorization is valid until the following date or event:

☐ Specify Date ___/___/____ ☒ End of the Study
☐ Other: _____ ☐ None; authorization is valid indefinitely

Efforts will be made to ensure that the Child's PHI will not be shared with other people outside of the research study. However, the Child's PHI may be disclosed to others as required by law and/or to individuals or organizations that oversee the conduct of research studies, and these individuals or organizations may not be held to the same legal privacy standards as are doctors and hospitals. Thus, the Research Team cannot guarantee absolute confidentiality and privacy.

As the Child's parent and/or legal guardian, I have the right:

1. To refuse to sign this form. Not signing the form will not affect the Child's regular health care including treatment, payment, or enrollment in a health plan or eligibility for health care benefits. However, not signing the form will prevent the Child from participating in the research study above.

2. To review and obtain a copy of the Child's personal health information collected during the study. However, it may be important to the success and integrity of the study that persons who participate in the study and their parents and/or legal guardians not be given access until the study is complete. The Principal Investigator has discretion to refuse to grant access to this information if it will affect the integrity of the study data during the course of the study. Therefore, my request for information may be delayed until the study is complete.

3. To cancel this release of information/authorization at any time. If I choose to cancel this release of information/authorization, I must notify the Principal Investigator for this study **in writing** at: Department of Pediatric Anesthesia, 702 Riley Hospital Dr., Room 2001. Indianapolis, IN 46202. However, even if I cancel this release of information/authorization, the Research Team, Research Sponsor(s) and/or the Research Organizations may still use information about the Child that was collected as part of the research project between the date I signed the current form and the date I cancel the authorization. This is to protect the quality of the research results. I understand that canceling this authorization may end the Child's participation in this study.

4. To receive a copy of this form.

I have had the opportunity to review and ask questions regarding this release of information/authorization form. By signing this release of information/authorization, I am confirming that I have the authority to execute this authorization on behalf of the Child.

_____
Printed name of Parent and/or Legal Representative

_____
Signature of Parent and/or Legal Representative *Date*

**If signed by a legal representative; state the relationship and identify below the authority to act on behalf of the individual's behalf.*
***Individual is:** ☐ a Minor ☐ Incompetent ☐ Disabled ☐ Deceased

***Legal Authority:**
☐ Custodial Parent ☐ Legal Guardian ☐ Executor of Estate of the Deceased
☐ Power of Attorney Healthcare ☐ Authorized Legal Representative
☐ Other: _____

Conventional Direct Laryngoscopy vs. Video Laryngoscopy With the C-MAC for Pyloromyotomy

IRB # 1306011553

CHECKLIST

- **All inclusion and exclusion criteria met** Yes ☐ No ☐
- **Informed Consent Obtained** Yes ☐ No ☐
- **Authorization for Release of Information** Yes ☐ No ☐
- **Documentation of Informed Consent Completed** Yes ☐ No ☐

Study and timeline of Interventions

1. All subjects must have IV access established preoperatively
2. New pulse oximeter probe will be placed on the subject's big toe upon arrival to the OR.
3. Orogastic suctioning with a 10fr. Salem sump done with the subject supine, right and left lateral positions
4. Pre-oxygenation with 100% for one minute
5. Rapid Sequence induction with Propofol 2.5mg/kg and Succinylcholine 2.5mg/kg IV
6. The anesthesia resident or fellow will mask the patient and the staff anesthesiologist will manually ventilate the patient maintaining airway pressures of less than 15mmHg
7. Direct laryngoscopy with a Miller blade or a CMAC 0 blade
8. Intubate patients with a 3.0 cuffed endotracheal tube, with a stylet
9. If the resident is having difficulty securing the airway, the staff may intervene at any time
10. Successful intubation when end tidal CO2x3 noted, chest rise adequate, and bilateral and equal breath sounds are heard
11. Maintain anesthesia with sevoflurane
12. Extubation at the conclusion of the case when extubation criteria met
13. Routine PACU care, pain, nausea and anxiety medicine as needed per direction of the of the anesthesia staff

There will be up to four data collection points during the patient's general anesthetic:

1. Level of resident training
2. Desaturation below 80% during induction
3. Staff intervention needed for intubation
4. Number of intubation attempts

Signature: _____ Date: _____

Date:_____

Intra-Operative Data Collection Form

(circle one under each column)

Resident Training Level	Desaturation Below 80%	Staff Intervention Required	# of Intubation Attempts	Method
CA1	YES	YES	1	CMAC
CA2	NO	NO	2	DIRECT
CA3			3	
FELLOW			4	
			5	

PACU Data

Any Complications in the PACU Yes ☐ No ☐

Croup? Yes ☐ No ☐

Require supplemental Oxygen? Yes ☐ No ☐

Adverse Event(s)

If Yes complete table below:

Adverse Event	Severity	Related to the study intervention	Treatment	Resolved
1.	Mild Moderate Severe	Yes ☐ No ☐		Yes ☐ No ☐
2.	Mild Moderate Severe	Yes ☐ No ☐		Yes ☐ No ☐

Signature: _____ Date: _____