INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR
King Vision Video Laryngoscope aBlade System for Use in Children

Your child is being invited to participate in a research study to collect data or information about a device used by the anesthesiologist during their surgery. Your child was selected as a possible subject because they are having a surgical procedure done at Riley Hospital for Children that will require general anesthesia. During this time, a breathing tube will be placed in your child's trachea (breathing or windpipe), and their breathing will be supported while they are asleep. We ask that you read this form and ask any questions you may have before agreeing for your child to be in the study.

The study is being conducted by Dr. Nicole Horn and her colleagues at Riley Hospital for Children.

STUDY PURPOSE

The purpose of this study is to collect visualization and endotracheal intubation data using the video device adapter and pediatric disposable blades and breathing tubes (made for children).

NUMBER OF PEOPLE TAKING PART IN THE STUDY:

If you agree to participate, your child will be one of 100 subjects who will be participating in this research at Riley Hospital for Children.

PROCEDURES FOR THE STUDY:

The methods and procedures for typical endotracheal tube placement with the facility will be followed without any deviation except for the use of the King Vision Video Laryngoscope. The breathing tube is required based upon your child's specific surgery, not because of this study. Data will be collected for the research study. The data collected will be used to verify the expected actions that need to be taken to use the King Vision Video Laryngoscope and will serve as a potential source for additional studies. Data will include your child's age, weight, height, and gender. It will also include performance scores and overall ratings of the use of the device from the anesthesiologist.

During direct laryngoscopy with no video system blade, the blade is inserted into the patient's mouth and a small amount of force is used to visualize the tracheal opening. It is our hope that the King Vision Video Laryngoscope does not require a direct line of site therefore suggesting that the anesthesiologist will use less force while placing the tube.

RISKS OF TAKING PART IN THE STUDY:

All medical products and procedures have some associated level of risk. In this study, the risks associated with the King Vision Video Laryngoscope are identical or less than other methods of tube placement. Within the frame of endotracheal tube insertion, your child is at the same risk as with standard forms of intubation. These risks include: mucosal (skin in the mouth and nose) injuries, perforations, tears, edema (swelling), sore throat, injuries to the jaw, and nerve injuries.

There is a minimal risk of loss of confidentiality. We will take all precautions to keep your child's records related to this study private.

BENEFITS OF TAKING PART IN THE STUDY:

We do not anticipate any benefit to your child in this procedure due to the use of the King Vision Video Laryngoscope. Participating in the study may not benefit you at this time. We hope to find out more information that will help other children in the future.

ALTERNATIVES TO TAKING PART IN THE STUDY:

Instead of being in the study, you can decide not to have your child participate. If you choose to not have your child be included in the study, this will not affect their care in any way. Your child will receive all standard, appropriate medical treatment at Riley Hospital for Children.

CONFIDENTIALITY

Efforts will be made to keep your child's personal information confidential. We cannot guarantee absolute confidentiality. Your child's personal information may be disclosed if required by law. Your child's 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 child's 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) who may need to access your child's medical and/or research records.

COSTS

The cost associated with your child's hospitalization stay will continue to be yours and your child's insurances responsibility. The study will not change the course of your child's care.

PAYMENT

You or your child will not receive payment for taking part in this study. Neither the investigator, nor the hospital will receive any compensation for your child's participation.

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study or a research-related injury, contact the researcher Dr. Nicole Horn at 317-944-8891. 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 317-944-5000 and ask the operator for the anesthesia staff on call.

For questions about your child's 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 your child is entitled. Your decision whether or not to participate in this study will not affect your current or future relations with Riley Hospital for Children.

Your child's participation may be terminated by the investigator without regard to your consent in the following circumstances: If the investigator feels it is in your best interest to be removed.

SUBJECT'S CONSENT

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

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

Subject's Printed Name:_____

Subject's Signature:_____ **Date**:_____

Printed Name of Parent:_____

Signature of Parent:_____ **Date**:_____

Printed Name of Parent:_____

Signature of Parent:_____ **Date:**_____

Printed Name of Person Obtaining Consent:_____

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