Boston Children's Hospital

RESEARCH CONSENT FORM

Use Plate or Print:

MRN#:

DOB:

Subject's Name:

Gender:

DO NOT PLACE IN MEDICAL RECORD

Protocol Title: Evaluation of Outcomes in the Post Anesthesia Care Unit at Boston Children's Hospital Waltham

Principal Investigator: Joseph Cravero, MD

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

You and your child are being asked to participate in a research study to evaluate your child's experience while in the Post Anesthesia Care Unit (PACU) at Boston Children's Hospital Waltham. In order to study this, we would like to ask you some questions about your child before and after surgery. These questions will ask for information on changes in your child's behavior before and after surgery, and about your child's recovery process after surgery. We hope this will help us to understand and improve PACU outcomes which may bring more satisfaction to patients, families and health care providers.

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

This observational research is being done at a single site, Boston Children's Hospital Waltham. The main study doctor from Boston Children's Hospital is anesthesiologist Dr. Joseph Cravero.

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

You are being asked to give permission for yourself and for your child to participate in this study. All patients 2-6 years of age, who are scheduled for any of the following qualifying surgeries at Boston Children's Hospital Waltham, can participate:

- Tonsil and/or Adenoid Removal
- Eye Muscle Surgery

Your child was identified by a member of our research staff because your child is scheduled for a surgery with one of these procedures.

Our study will take place over 24 months. We do not have a specific number of patients that we will study..

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

If you choose to participate in this study, you will be asked to complete some behavioral and satisfaction questionnaires, allow the study team to observe part of your child's anesthesia care and to record some information from your child's electronic medical record. You will also be asked to provide some contact information (so we can help you complete some questionnaires after your child's surgery as described below) and some background information such as your/your child's demographic and family history. Any information we collect will be de-identified and reported in aggregate to protect your privacy. Study activities are described in detail below and a summary of who completes which questionnaire is summarized in table 1.

Background information Questionnaire

You will be asked to fill out an informational form asking about marital status, education and employment.

Behavior Questionnaires

Before surgery, you will be asked to complete a questionnaire describing your child's behavior. Then, 2 days after surgery and again, 2 weeks after surgery, you will be asked to complete another set of questionnaires, describing changes to your child's behavior since being discharged from the hospital.

The questionnaires about your child's behavior changes after being discharged from the hospital will be sent to you by email and you will be asked to answer the questionnaires using a secure, online platform called REDCap. If you prefer, you do have the option to complete these questionnaires on paper instead of by email. If you choose to complete a paper version of the questionnaires, the research team will give them to you when you/your child are ready to go home after surgery. The questionnaires will be in self-addressed, stamped envelopes for convenience. The research staff will ask your preference when they collect your contact information before surgery. Regardless of the method you choose to complete the questionnaires, a member of the research team will call to remind you to complete each questionnaire when it is due. If you choose to complete the questionnaires by email you will be called if we have not received it within 4 days after discharge, and again, 2.5 weeks after discharge, if we have not received the 2 week questionnaire by then. If you choose to complete the questionnaires on paper you will be called if we have not received them 2.5 weeks after discharge. Additionally, you will be given the opportunity to complete the questionnaires over the phone, at the time of the reminder phone calls, if you so choose. Each questionnaire will take approximately 5-10 minutes to complete.

A member of the study team will evaluate these questionnaires to see if your child exhibited any new behaviors after surgery.

Perioperative Observation

A member of the research team will observe and record your child's behavior related to their anxiety about his/her upcoming surgery, while he/she undergoes the pre-operative process.

If your child's anesthesia care provider induces (starts) anesthesia using a mask technique, a member of the research team will observe and record how calm he/she is feeling, and how easily your child falls asleep during that process. If another technique is used to induce anesthesia (for example, if the induction is performed with an IV) the scale used to record how calm your child is during this process does not apply to the situation and cannot be used. In this case, the study team would not observe this part of your child's surgery.

Satisfaction Questionnaires

Two days, and again, two weeks after surgery, you will be asked to complete a short satisfaction survey. These questionnaires will be completed along with the post-surgery behavior questionnaires, and will be provided via email or on paper as described in the *Behavioral Questionnaires* section.

Information from the Medical Record

The information we will record from your/your child's medical record includes: demographic information (age and weight), medical history (diagnosis, history of previous surgery (yes/no), and coexisting major medical problems), information about your/child's anesthesia care during surgery, information about your/your child's recovery in the PACU (pain, nausea/vomiting, how calm you/your child is when you/he/she wakes up, complications due to the anesthesia or surgery).

Table 1.

Questionnaire Type	**When is this filled out?**
Background Information	The day of surgery, before the surgery starts.
Behavior	• The day of surgery before the surgery starts • 2 days after surgery • 2 weeks after surgery
Satisfaction	• 2 days after surgery • 2 weeks after surgery

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

This study will not affect any part of your child's treatment during surgery or postoperative care.

Possible risk of breach of confidentiality: We will take all measures possible to protect the information we collect about your child during the perioperative time period at Boston Children's Hospital. We will keep all information that is on paper in a secure, locked environment. Any information that is kept on the computer will be kept in a secure manner to minimize the chance that anyone could obtain access to the information. In spite of our efforts, there is always a chance that some of the information on your child's health could be seen by someone not associated with this study. If this happened and we knew about it, you would be informed.

What are the benefits of this research study?

There will be no direct benefit to your child from participating in this study. We believe that results of this study may help us improve our quality of perioperative care, thereby decreasing the chance of possible injuries to other children and increasing our families and patients' satisfaction with their surgery.

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

There are no costs for participating in this study. You will not be paid for participating.

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

Participation in this study is voluntary. If you choose not to participate, your child will receive standard clinical care. Refusal to participate will not interfere with your child's current or future care received at Boston Children's Hospital.

What are my rights as a research participant?

Participation in this study is voluntary. You may refuse or your child may refuse to participate or may withdraw from the study at any time without penalty or loss of benefits and without affecting treatment of your child's medical care.

Are there other things I should know about?

At the completion of this study, your child's study data will be given a unique identification number and stored without your child's name or other identifiers. Only the investigator will have a list to know which information is linked to your child and this list will be kept confidential in a secure location.

Why would I be taken off the study early?

There are a few circumstances where you might enroll your child in this study and your child would not complete the study. These include:

- The study is cancelled.
- You/your child do not complete the questionnaires required for the study.

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 not be placed in your child's medical record.

The results of the tests performed for research purposes will not be placed in your/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.

HEALTH INFORMATION PORTABILITY AND ACCOUNTABILITY ACT (HIPAA):

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 child's care at Boston Children's Hospital now or in the future and there will be no penalty or loss of benefits. You andyour 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 andyour 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.

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: **Joseph Cravero, MD**	Phone: 617-355-6457 Pager: 617-355-7243 [Pager # 6310]	▪ General questions about the study ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints
Study Contact: **Nissa Askins, MPH**	Phone: 857-218-5638 Pager: None.	▪ 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** or **Legal Guardian** Relationship to child

■ 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 Subject (if applicable)

■ _____ _____

Date (MM/DD/YEAR) Signature of **Adult Subject** *(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 subject or legal representative, **or**

☐ The individual has certain communication impairments that limit the subject'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 subject, 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