Boston Children's Hospital

RESEARCH CONSENT FORM

Use Plate or Print:

MRN#:

DOB:

Pt Name:

Gender:

DO NOT PLACE IN MEDICAL RECORD

Protocol Title: Pediatric Anesthesia Care Unit (PACU) Outcome Evaluation Project

Principal Investigator: Patcharee Sriswasdi, MD

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

You/your child are being asked to participate in a research study to evaluate you/your childôs experience while in the Post Anesthesia Care Unit (PACU) at Boston Childrenôs Hospital. In order to study this, we would like to ask you/your child some questions before and after surgery. These questions will ask for information on you/your childôs behavior, and about the 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 Childrenôs Hospital. The main study doctor from Boston Childrenôs Hospital is anesthesiologist Dr. Patcharee Sriswasdi.

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

You/your child are being asked to give permission to participate in this study. All patients who are scheduled for any of the following qualifying surgeries at Boston Childrenôs Hospital can participate:

- **Genito-Urinary/Urology Department**
  Circumcision, Orchidopexy, Hypospadias Repair, Hernia Repair, Cystoscopy, Pyeloplasty, and Ureteral Reimplants or Ureteral Stents
- **Otolaryngology Department**
  Tonsil and/or Adenoid Removal, Tympanostomy, Tympanoplasty, Mastoidectomy;
- **Orthopaedics Department**
  Hip or Knee Arthroscopies, Hardware Removal, or Tendon Lengthening
- **Plastic Surgery Department**
  Alveolar Cleft Repair

Patients undergoing these procedures who are having any of the following companion surgeries performed at the same time are also eligible: laryngoscopy, bronchoscopy, inguinal herniorrhaphy, or excision of the appendix epididymis. Your child was identified by a member of our research staff because your child is scheduled for a surgery with one or more of these procedures.

Our study will take place over 12 months. We do not have a specific number of patients that we will study, but we are hoping to enroll up to 400 ï 600 patients between the ages of 6 months and 30 years.

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

If you/your child choose to participate in this study, you will be asked to give us information about your or your childôs behavior and development by answering a short questionnaire either before or on the day of your surgery. This questionnaire will take approximately 5 - 10 minutes to complete. Your parents will fill out an informational form asking about marital status, education, and employment. This information may be reported in publications from this study. We also may ask you/your parents to complete an optional second questionnaire, anonymously and confidentially, that asks for an opinion of the relative importance, for you/your

child specifically, of factors associated with the anesthesia recovery process. These factors include pain management, nausea or vomiting, confusion, and breathing or cardiac emergencies. This questionnaire will take approximately 5 additional minutes to complete.

_____ (please check) YES, I agree to complete the optional questionnaire rank-ordering factors associated with the anesthesia recovery process.

_____ (please check) NO, I do not want to complete this optional questionnaire.

If your child is between 2 and 12 years, the person who signs your child up will observe how calm s/he is feeling before surgery. If you/your child is having hip or knee surgery and is 10 years old or older, you/your child will be asked to rate average pain and also indicate if taking any medications for pain. The research team will collect information on how easily you/your child goes to sleep using an observational scale that the operative anesthesia team or a research assistant will complete. After your surgery is done, we will collect data from you/your anesthesia record on the type of medication given for pain and anesthesia and put it in a database with the other information about you/your child. Later, the research team will collect information (from the nursing record) about how you/your child felt while in the PACU. Specifically we will collect the data on pain management, nausea, vomiting or confusion that you or your child may experience during recovery.

When you/your child are ready to go home after surgery, the research team will give you/your parents a questionnaire to fill out to answer questions about your/your childôs progress after surgery if you are between the ages of 6 months ï 12 years. You will complete a survey about whether you feel any stress after having surgery if you are between the ages of 13 ï 30 years. You/your parents will be asked to fill out the questionnaire once two days after your/your childôs surgery and once more two weeks later. These questions will also ask how satisfied you/your parents feel with your/your childôs experience. The questionnaires will be in self-addressed, stamped envelopes for convenience. A member of the research team will call to remind you to complete these forms. We will evaluate these forms to see if you/your child exhibited any new behaviors after surgery. If you report not feeling well from stress, a psychologist will contact you or your parents to discuss how we might help you feel better. Data will be stored with all of the other information on how you or your child did before, during, and after the surgery. After these questionnaires are received, a member of the study team will send you a postcard letting you know your participation is complete and thanking you/your child for being in the study.

The questionnaires that are part of this study include:

Time Point	Information	Time for Completion
Before surgery	Surveys on you/your childôs behavior and the rank-order importance to you of anesthesia recovery factors.	10 minutes.
Right after surgery	Nursing record information on you/your childôs surgery experience.	None.
Two days after surgery	A survey on you/your childôs behavior or any stress after surgery.	10 minutes.

	A survey on you/your childôs satisfaction with your experience in recovery.	
Two weeks after surgery	The same surveys as two days after surgery.	10 minutes.

What are the risks of this research study?

This is an observational study which will not affect any part of you/your childôs 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 Childrenôs 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 childôs 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 you/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 patientsôsatisfaction 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 you or your childôs 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 for your child to participate or may withdraw from the study at any time without penalty or loss of benefits and without affecting treatment of your childôs medical care.

Are there other things I should know about?

At the completion of this study, your childôs study data will be given a unique identification number and stored without your childôs name or other identifiers. Only the investigator will have a list to know which information is linked to you or 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/your child might enroll in this study and you/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.

- There is withdrawal of parent/legal guardian permission for completing the study.

Other information that may help you

Boston Childrenôs Hospital has recently developed a web-based, interactive educational program for parents called ñA Parentôs Guide to Medical Research.ò To find out more about research at Childrenôs Hospital, please visit the program at www.researchchildren.org.

Boston Childrenôs 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 you/your childôs medical record.

The results of the tests performed for research purposes will not be placed in your/your childôs 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 childôs 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 Childrenôs Hospital involved in this study
- Medical staff at Boston Childrenôs 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 Childrenôs Hospital who oversee, advice, 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 Childrenôs 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 Childrenôs 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 Childrenôs 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 does 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 care or your childôs care at Boston Childrenôs Hospital now or in the future and there will be no penalty or loss of benefits. You/your child can withdraw from the study and end your permission for Boston Childrenôs 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/your 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 Hospitalôs Privacy Officer at 857-218-4680.

CONSENT/AUTHORIZATION

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 callé	At	If I have questions or concerns about
Investigator: Patcharee Sriswasdi, MD	Phone: 857-218-5779 Pager: 617-355-7243 [Pager # 4876]	▪ General questions about the study ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints
Study Contact: Elizabeth Carpino, MA	Phone: 857-218-5790 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 <u>any</u> research activities.
- I give permission for my/my childôs participation in this research study and for the use of associated protected health information as described above (HIPAA).

<u>Parent/Legal Guardian Permission (if applicable)</u>

If the child to be involved in this research study is a <u>foster child</u> or a <u>ward of the state</u> please notify the researcher or their staff who is obtaining your consent.

■ _____ _____ _____

Date (MM/DD/YEAR) Signature of **Parent #1** or **Legal Guardian** Relationship to child

■ If child/adolescentôs assent is not obtained, 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: _____.

<u>Adult Subject (if applicable)</u>

■ _____ _____

Date (MM/DD/YEAR) Signature of **Adult Subject** *(18+ years)*

ADULT SUBJECT - if decisionally impaired (if applicable)

Legal Authorized Representative/Guardian

I give permission for the person I am authorized to represent to participate in this research study and for the use of associated protected health information as described above (HIPAA).

■ _____ _____ _____

Date (MM/DD/YEAR) Signature of **Legal Guardian** Print Name

■ Relationship to Subject * (*This order must be followed. If there is a court appointed guardian, this is who needs to provide consent. If not, a health care proxy, followed by durable power of attorney and lastly, family members)*

☐ Court-Appointed Guardian
☐ Health Care Proxy (Attach Proxy and ensure there is express authority to make health care decisions inclusive of research.)
☐ Durable Power of Attorney (POA) (Durable POA may be limited to specific areas. Attach Durable POA and ensure it covers research.)
☐ Family Member/Next of Kin, (*in order of preference: spouses, parents and adult children)*
Specify relationship_____

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 hospitalôs privacy notification (if requested)

■ _____ _____

Date (MM/DD/YEAR) Signature of **Investigator or Associate**

Witness Statement & Signature

Required ONLY IF (check which one applies):

☐ Consent document needs to be read to subject or legal representative, **or**
☐ Communication impairments limit the subjectôs ability to clearly express consent, **or**
☐ Other reason: please specify _____

I confirm that the information in this consent form was accurately explained to, and understood by the subject, parent and/or legally authorized representative as required, and that informed consent was given freely.

■ _____ _____

Date (MM/DD/YEAR) Signature of **Witness**