Boston Children's Hospital

RESEARCH CONSENT FORM

Use Plate or Print:

MRN#:

DOB:

Pt Name:

Gender:

Protocol Title: Validation of the Pediatric Sedation State Scale (PSSS) (**Patient Participants**)

Principal Investigator: Joseph P. Cravero, MD

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

You/your child are being asked join a research study at Boston Children's Hospital. We are making a new survey that may tell us how well you/your child feels when going to sleep or becoming numb ("is being sedated") in the following hospital clinics: Radiology (including Interventional, CT, and Nuclear Medicine); Dentistry; Oral Surgery/Plastics; Otolaryngology; the Gastrointestinal Procedure Unit, and the DFCI-BCH Jimmy Fund Clinic. This new survey is called the Pediatric Sedation State Scale (PSSS). It was developed by a team of doctors who give and study how to give sedation better. We want to test it on patients like you to see if it measures how you feel while asleep. We think the PSSS can tell us how safely you/your child feels when being sedated in the hospital clinics we have listed, no matter what procedure you/your child has. If the testing is successful, we think it may help doctors and nurses give sedation better both here at Boston Children's Hospital and, eventually, in other hospitals and clinics. This may make more patients, families, and doctors feel better about the sedation that is used for the kinds of procedures you/your child may be having.

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

This study is being done at Boston Children's Hospital on both the Longwood and Waltham campuses. The main study doctor from Boston Children's Hospital is anesthesiologist Dr. Joseph P. Cravero.

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

You/your child are being asked to give permission to be in this study. All patients who are having sedation in the clinics identified above can be in the study. You/your child were identified by a member of our research staff because you/your child are scheduled to have sedation in one of these clinics.

Our study will take place over 28 months. We do not have a specific number of patients that we will study, but we are hoping to enroll up to 80 patients between the ages of 0 and 21 years.

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

If you/your child decide to be in this study, you will be asked to let us film while you/your child's gets sedation in any one of the clinics identified above. We want to film from when you/your child gets sedation until when you/your child wakes up or recovers. We want to collect information on which clinic you/your child had sedation and what procedure you/your child had. We will ask a team of 25 doctors and nurses to 'rate,' or describe the quality, of your/your child's time asleep or numb by carefully watching 30-second clip(s) from your video and 'rating' it (or giving it a score on the PSSS). We will compare these first scores to second scores that the same doctors and nurses will give to your 30-second video clip using a survey that we already know can measure how well you/your child feels while asleep. This survey is called the COMFORT® scale. This second rating should tell us whether the PSSS really can measure how well you/your child feels while going to sleep after anesthesia. We will combine all of this information to understand whether the new survey – the PSSS – is good at measuring how well children feel after having sedation in any of the clinics mentioned above.

With your permission, we will film from the beginning to the end of the period you/your child gets sedation. These tapes may be as long as several hours. We will pull out only 30-second clips from your video for our doctors to use to describe the quality of your/your child's time asleep or numb. The original, or complete, video will be destroyed no more than two weeks after we film it. We will keep the 30-second clip(s) until the end of the project, after all of our doctors have rated it. This period may be for as long as two years.

What are the risks of this research study?

This is an observational study only, which will not affect any part of you/your child's care before, during, or after getting sedation. Your/your child's care and sedation will be exactly the same as it would be if you/your child were not in the study.

The primary risk of this proposed video library is to your/your child's confidentiality. 'Confidentiality' means that nobody should be able to see your study information except the doctors, nurses, and staff who are working on the study. We will do everything possible to protect the information we collect about you/your child. We will keep all of the information that we collect on paper in a safe, locked environment. Any information that is kept on the computer will be kept in a safe manner to try to make sure nobody can see or get it. Videos will only be viewed by people who are doing the study. Videos will be stored on secure computers that the principal investigator, research and data coordinators maintain.

No matter what we do, there is always a chance that some of the information on your/your child's health could be seen by someone not working with 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 being in this study. We believe what we learn from this study may help us make our sedation better for all patients and families undergoing care requiring anesthesia in Radiology (including MRI, Interventional, CT, and Nuclear Medicine), Dentistry, Oral Surgery/Plastics, Otolaryngology, the Gastrointestinal Procedure Unit, and the DFCI-BCH Jimmy Fund Clinic. This may make patients like you, as well as your family, feel better about having sedation for this kind of care at Boston Children's Hospital.

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, you/your child will get the same care as you would get now and in the future if you were not in the study in any of the clinics in the study and 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 be in the study or leave the study at any time without penalty or loss of benefits and without affecting treatment of your/your child's medical care.

Are there other things I should know about?

At the end of this study, your/your child's study information will be given a distinct identification number so that the information can be stored without your/your child's name or other identifiers. Only the main study

doctor will have a list to know which information is linked to you or your child. This list will always be kept secret in a secure location.

During the time we keep the video and clip(s), they will be protected on a secure, password-protected computer drive that only the head researcher for this study and his research staff (e.g., a research coordinator or assistant, a computer programmer) can access.

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.
- There is withdrawal of patient/parent/legal guardian permission for completing 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 you/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, 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 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 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 child's care at Boston Children's 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 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/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 Hospital's 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 call…	At	If I have questions or concerns about
Investigator: Joseph Cravero, MD	Phone: 857-218-4824 Pager: 617-355-7243 [Pager #6310]	▪ 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 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 #1** or **Legal Guardian** Relationship to child

■ If child/adolescent's 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: _____.

Adult Subject (if applicable)

■ _____ _____

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 hospital's 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 subject's 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**