



Use Plate or Print:

MRN#:

DOB:

Pt Name:

Gender:

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

**Principal Investigator:** Joseph Cravero, MD

**Why are we doing this research study?**

We want to tell you about a research study we are doing. A research study is a way to learn more about something – in this case about whether a new survey we have made called the Pediatric Sedation State Scale (PSSS) can tell us how good and safe you feel and respond when given sedation for a medical procedure. You may be in the study if you are having a medical procedure requiring sedation 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. Eventually, using the PSSS regularly may help improve the quality and safety of all sedation procedures in these settings at Boston Children's Hospital and, ultimately, at other healthcare centers, thereby creating a higher level of service and satisfaction for patients, family, and health care providers.

**What do I have to do?**

We will ask you and your family for permission to film while you are sleeping or feeling numb in any of the clinics named above from the time you get sedation and fall asleep until the time you wake up. Once we have the video, we will pull out 30-second clip(s) that can show us how you were feeling while asleep or numb. We will work with a team of 25 doctors and nurses to 'rate,' or describe the quality, of your time asleep or numb by carefully watching the 30-second clip(s) from your video and rating it with the PSSS. We will compare the ratings to values from a well-established survey called the COMFORT® scale to see if the PSSS measures what we think it measures. We also want permission to collect information on which clinic you were in and what procedure was done. We will combine all of this information to understand whether the new survey – the PSSS – is good at measuring the quality of your time asleep if you are getting care in any of the clinics listed above. We will get rid of the full videos we take of you no more than two weeks after we take it. We will keep the 30-second clip(s) until the end of the study, or no more than two years later.

**Are there risks in this study?**

Being part of this study will not change anything about how your sedation for your procedure is performed, or how you are treated before or after the procedure. Being part of this study does not mean you will be at any increased risk or the amount of discomfort you have during or after your operation will change. This is why we believe the risks for being in this study are very low.

**Do I have to do this?**

You do NOT have to join this study. You can say "no" right now or you can say "OK" now and change your mind later. All you have to do is tell us if you want to stop. No one will be mad at you if you don't want to be in the study or if you join the study and change your mind later and stop.

Before you say yes or no to being in this study, we will answer any questions you have. If you join the study, you can ask questions at any time. Just tell the researcher you have a question.

If you have any questions about this study, contact Dr. Joseph Cravero. He may be reached at 857-218-4824.

If you sign your name below, it means that you agree to take part in this research study.



**Boston Children's  
Hospital**

**RESEARCH ASSENT FORM**

MRN: \_\_\_\_\_

Pt Name: \_\_\_\_\_

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**Child/Adolescent Assent**

■ \_\_\_\_\_  
Date (MM/DD/YEAR)

\_\_\_\_\_  
Signature of **Child/Adolescent Subject**