



Clinical Research Study

**For patients receiving
anesthesia in the following
hospital clinics:**

- **Radiology**
- **Dentistry;**
- **Oral Surgery/Plastics;**
- **Otolaryngology;**
- **Gastrointestinal
Procedure Unit (GPU);
and**
- **Jimmy Fund Clinic**

**Boston Children's Hospital
Harvard Medical School**

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Validation of the Pediatric State Sedation Scale (PSSS)

What is this study about?

Doctors at Boston Children's Hospital are developing a new survey called the Pediatric State Sedation Scale (PSSS) to assess the safety and quality of anesthesia care for youth having procedures with anesthesia in any of the following clinics: Radiology (Interventional Radiology, CT, and Nuclear Medicine), Dentistry, Oral Surgery/Plastics, Otolaryngology, the Gastrointestinal Procedure Unit (GPU), and the Jimmy Fund Clinic.

Safe, effective anesthesia care for medical procedures throughout Boston Children's Hospital is one standard of premier hospital care. The anesthesia care provided throughout the hospital should be performed well and safely in every clinic and during all procedures requiring anesthesia. We believe the Pediatric State Sedation Scale (PSSS) will tell us about the quality of patients' anesthesia for procedures across the range of clinics and procedures done throughout the hospital where anesthesia is used.

Once developed, use of the Pediatric Sedation State Scale (PSSS) should improve the safety of hospital-wide sedation, bringing more satisfaction to patients, families, and other health care providers.

What will I be asked to do?

If you or your child agree to participate in this study, we will ask you/your child if we can videotape you/your child during her or his sedation, from the time of falling asleep to waking up. We will watch some portion of these video clips (specifically, 30-second vignettes) very carefully to learn whether the Pediatric State Sedation Scale (PSSS) can be used reliably to understand the quality of the anesthesia care you/your child received.

We will also ask a team of 25 expert anesthesia providers to both (1) rate your/your child's 30-second video clips using the Pediatric State Sedation Scale (PSSS) and (2) compare these ratings to scores obtained from a commonly used survey for understanding anesthesia quality called the COMFORT® scale. These comparisons will tell us whether the PSSS is measuring the quality of your/your child's anesthesia in the way we think it is.

This study will not interfere with any aspect of your or your child's treatment while at Boston Children's Hospital. Whether you choose to participate or not will have no effect on your or your family's current and future care at Boston Children's Hospital.

Who is conducting this research study?

Anesthesiologist Joseph P. Cravero, MD and his anesthesia research colleagues are conducting the study.

How do I learn more about the research?

To give you more detailed information about this study, we have included the study's consent, or permission, form in this mailer for you to review. A study coordinator will call you up to 3 days before your/your child's procedure to discuss the study and answer any questions. S/he will meet you to see if you want to be in the study before your/your child's procedure. If you do, s/he will ask you to sign the consent form then. **If you/your child does not want to be in the study then or at any time later, you may always tell the research coordinators or researchers doing the study, the doctors, or the nurses involved in giving you/your child anesthesia that you/your child does not want to be or continue being in the study.**

If you have any questions about the study, please contact our study coordinator, Elizabeth Carpino, or the Principal Investigator, Joseph P. Cravero, MD. Your participation is completely voluntary. You may change your mind at any time and withdraw. All of your research data will be kept confidential as required by law.

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