



Boston Children's Hospital
Until every child is well™



**HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL**

**Welcome to our presentation on
a research study currently underway at
Boston Children's Hospital!**



Boston Children's Hospital
Until every child is well™



HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

A Pilot Study of Dexmedetomidine-Propofol in Children Undergoing Magnetic Resonance Imaging



Boston Children's Hospital
Until every child is well™

Who is doing this research study?

Where is it being conducted?

Who?

Dr. Joseph Cravero in the
Boston Children's Hospital's
Department of Anesthesiology



Where?

The "MRI scanner" at Boston
Children's Hospital





Boston Children's Hospital
Until every child is well™



What is the "MRI scanner" ?

The "MRI scanner" is a large, tube-shaped magnet that provides a strong magnetic field around the person being scanned. Computers make pictures of the part of the body that is being scanned with the information that is collected by the scanner.



Boston Children's Hospital
Until every child is well™

What are we studying?



- Patients in the MRI scanner must be very still so the computer can make a clear picture.
- At an MRI scan, another doctor called an anesthesiologist is there to help the patients stay still by giving them medicine to help them sleep during the MRI scan.



Boston Children's Hospital
Until every child is well™

What are we studying?



- There are many different kinds of medicine an anesthesiologist may use to help patients sleep. We want to learn more about a specific combination of two types of **medicine**: dexmedetomidine and propofol.



Boston Children's Hospital
Until every child is well™

Are these medicines safe?

- Propofol and dexmedetomidine are both used routinely to help children sleep during an MRI scan.



Boston Children's Hospital
Until every child is well™

Why are we studying these medicines?

- We are always looking to understand better ways to give safe and effective care to our patients. We would like to find out if giving children dexmedetomidine and propofol together in specific amounts will help children sleep long enough to finish their MRI scan.



Boston Children's Hospital

Until every child is well™

What will I be asked to do?

- You will be asked to allow us to administer specific amounts of dexmedetomidine and propofol to your child to help them to sleep during their MRI
- You will be asked to give the research team permission to record information from your child's medical record, and to observe your child's care when you come to Boston Children's Hospital for his or her MRI Scan.
- You will be asked to give permission for the anesthesia doctor to care for your child with a combination of dexmedetomidine and propofol during his or her MRI scan.



Boston Children's Hospital
Until every child is well™

What kind of information is being collected?



Before your child's MRI scan we will gather information about

- your child's medical history from his or her electronic medical record.



Boston Children's Hospital
Until every child is well™



What kind of information is being collected?

During your child's MRI scan, we will collect information on:

- the time the anesthesiologist begins giving your child medicine
- the time your child is ready to begin the MRI scan
- how much medicine your child receives
- information on the way your child's body responds to the medicine



Boston Children's Hospital
Until every child is well™

What kind of information is being collected?



After your child's MRI scan:

- your child's recovery in the "Post Anesthesia Care Unit" (We call this area the PACU)
- the time your child wakes up after the MRI scan
- the time your child's doctor says you are ready to go home





Boston Children's Hospital
Until every child is well™

What will we learn?

- We hope to learn whether or not this specific combination of dexmedetomidine and propofol can help children sleep while they are having their MRI scans.





Boston Children's Hospital

Until every child is well™

How will participating in this study change my child's care?

- *Whether or not you choose to participate in this study, your child will still have his or her MRI scan as planned, and your child will have care from an anesthesia doctor as planned. The care your child receives will not change in any way if you decide not to participate in this study.*
- *If you choose to participate in this study, your child's anesthesia doctor will use a specific combination of dexmedetomidine and propofol for your child's anesthesia care during his or her MRI scan.*
- *If you choose not to participate in this study, your child's anesthesia doctor may give him or her a combination of propofol and dexmedetomidine (which may be the same or different from the study combination) OR the anesthesia doctor may give him or her a different type of medicine.*



Boston Children's Hospital
Until every child is well™

Who can be in this study?

Patients who:

- Are between 1 and 12 years old
- Have an MRI scan scheduled at Boston Children's Hospital
- Are deemed by their anesthesia doctor to be good candidates for treatment with dexmedetomidine and propofol.





Boston Children's Hospital
Until every child is well™

Are there risks?

Dexmedetomidine and propofol are used for patients whether or not they are participating in a research study. This means the risks will not change if you choose to participate in this study.





Boston Children's Hospital

Until every child is well™

What are the risks?

- When an anesthesia doctor uses dexmedetomidine and propofol, some patients experience known drug side effects, or pain, bruising and anxiety when the doctor puts in the IV needle.
- More concerning, but rare side effects associated with these drugs include :
 - Obstruction of the airway
 - Shallow breathing
 - Slow heart rate
 - Low blood pressure
 - Allergic reactions
- All of these effects are manageable by the trained anesthesiologists who are managing your child at Boston Children's Hospital.



Boston Children's Hospital
Until every child is well™

What are the risks?

- A small risk is associated with keeping your survey and electronic medical information private.

- Our precautions for this:



1. All paper information will be securely locked;
2. All computer information will be protected on private hospital servers.



Boston Children's Hospital
Until every child is well™

Protecting Your Privacy

In the unlikely event any information on your child's health could be seen by someone not associated with this study you would be informed if the research team became aware of this.





Boston Children's Hospital

Until every child is well™



HIPAA
Compliance

Health Information Portability and Accountability Act (HIPAA)

- **HIPAA is a law that says we must keep your child's medical record *confidential*.**
- **Only people involved in the study will see your family and your child's personal information.**
- **We will remove *all* names, birthdate, and other identifying information when analyzing and reporting the study data.**



Boston Children's Hospital
Until every child is well™

Participating is Voluntary



- You and your child may decide whether or not to be in this study.
- If you choose to participate, you and your child will receive exactly the same care as if you decided not to be in the study.



Boston Children's Hospital

Until every child is well™

- You or your child may stop being in the study *at any time* (by letting any of your doctors, nurses, or a research coordinator know).



At that point, we would stop collecting information.



Boston Children's Hospital

Until every child is well™



**HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL**

It is a privilege to invite you and your child to join in this research.



By enrolling, you and your child will contribute to important knowledge about options for providing safe and effective care for children getting anesthesia care.

