



Use Plate or Print:

MRN#:

DOB:

Pt Name:

Gender:

***DO NOT PLACE IN
MEDICAL RECORD***

Protocol Title: Society for Pediatric Anesthesia
Improvement Network (SPAIN) Chest Wall
Deformity Project

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 how well you feel before, during, and after having corrective surgery for the chest wall deformity known as pectus excavatum (PE). We are working with several other children's hospitals to combine medical and surgical information from youth like you who are having and recovering from PE corrective surgery at Boston Children's Hospital with the same information from youth having the surgery at the other hospitals. By putting all this information in one database, we will have more information on lots of youth having PE corrective surgery and hope to be better able to study and ultimately improve surgical care for all youth having PE corrective surgery. We hope results from this study will lessen the chance of injuries or pain to other children and increase patients' satisfaction with their operations.

What do I have to do?

We will ask you and your family for permission to collect, record, and report your treatment and recovery information from before, during, and after having PE corrective surgery for inclusion in the one database. This information is in your electronic medical and surgical records. You will be asked to tell us about any stressful behaviors by filling out a behavior survey at two weeks and three months afterwards. We will also ask you to tell us about any pain you may have, medicines you are taking for pain, and whether there have been any changes in your physical activity (like going to school or playing sports) since your operation. These surveys will be in self-addressed, stamped envelopes so that you can mail them back easily. You can also complete the surveys over the telephone instead. Someone who works with us will call you to collect this information.

Are there risks in this study?

Being part of this study will not change anything about how your PE corrective surgery is performed, or how you are treated before or after the surgery. 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 857-218-5779.

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

Child/Adolescent Assent

■ _____
Date (MM/DD/YEAR) Signature of **Child/Adolescent Subject**