Boston Children's Hospital

RESEARCH CONSENT FORM

DO NOT PLACE IN MEDICAL RECORD

Use Plate or Print:

MRN#:

DOB:

Pt Name:

Gender:

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

Principal Investigator: Joseph Cravero, MD

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

You/your child are being asked to participate in a research study at Boston Children's Hospital designed to create a multi-hospital electronic database for collecting and studying medical and safety information related to having corrective surgery for the chest wall deformity known as Pectus Excavatum (PE). **PE** is the most common deformity of the chest in which several ribs and the sternum may grow abnormally. This causes a caved-in or sunken appearance of the chest that can either be present at birth or not develop until puberty. Surgical treatment for PE can involve either invasive or minimally-invasive techniques; currently, the two most common techniques are either the Ravitch (invasive) or Nuss (minimally-invasive) procedures.

We have identified you as someone who might want to be in this study because you or your child is scheduled at Boston Children's Hospital for a surgical procedure – for example, either the Ravitch or Nuss procedure – on the chest wall region to correct PE deformities. Because corrective surgery for PE is not done often at any single children's hospital, we would like to combine your/your child's medical, safety, and recovery information from having the surgery at Boston Children's Hospital with the same information collected from patients having the surgery at up to 20 participating child academic medical centers. To create the database, we would like to review your/your child's medical records before, during and after having the corrective surgery. We would like to ask you/your child to complete surveys on psychological and pain symptoms and any potential changes to physical functioning that you/your child may experience as a result of having the surgery at two weeks and three months afterwards. We hope to learn more about pain and safety outcomes related to the surgical techniques and the methods of pain control/management that are used before, during, and after your/your child's surgery and recovery. By collecting and analyzing this medical, surgical, and behavioral information from up to 20 child academic medical centers in a single database, we hope to be able to better understand and improve surgical care for all patients undergoing correction of PE in ways that cannot be accomplished by collecting this information from only the few youth treated at any single hospital. This study should allow for the development of national best practice recommendations for medical providers and lead to increased wellbeing and satisfaction among patients and their families undergoing surgical correction for PE.

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

This observational research is being done initially at six participating sites, including Boston Children's Hospital. Boston Children's Hospital will be the primary coordinating site. This means that the research team at Boston Children's Hospital will monitor recruitment and the collection and management of medical information at all of the other sites. Once the process for collecting and managing the medical information for the study has been developed as well as possible, , we will enroll up to 14 other participating institutions. Information from all sites will be kept in a single study database managed at the Dartmouth Bioinformatics Group at New Hampshire's Dartmouth College. The main study doctor from Boston Children's Hospital is anesthesiologist Dr. Joseph Cravero.

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

You/your child are being asked to give permission to participate in this study. All patients who are scheduled for surgical procedures on the chest wall region performed to correct pectus excavatum (PE) deformities at Boston Children's Hospital can participate. Your child was identified by a member of our research staff because your child is scheduled for PE corrective surgery.

Our study will take place over 18 months. We do not have a specific number of patients that we will study, but we are hoping to enroll up to 250 patients between the ages of 8 and 30 years.

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

If you/your child choose to participate in this study, you will be asked to give us permission to collect, record, and report treatment and recovery information from your medical/surgical records for corrective surgery for PE at Boston Children's Hospital for inclusion in the multi-site database. This information will come from a variety of Hospital record sources including your/your child's pre-operative assessment, the operating room records, the electronic anesthesia record, the electronic medical chart, and any related quality improvement reports collected at the time of surgery. You will be asked to give us permission to collect limited demographic information (e.g., gender, date of birth, admission/discharge details, date of surgery). You/your child will be asked to complete a postoperative stress assessment at two weeks and three months after having surgery. We will also ask you/your child to rate levels of pain, any medications you are taking for pain, your level of physical functioning at two weeks and three months after having surgery. The questionnaires will be in self-addressed, stamped envelopes for your/your child's convenience, so that you can mail them back most easily to Boston Children's Hospital. A member of the research team will call to remind you to complete these forms. Alternatively, you may elect to complete these forms over the telephone with a member of the research team. This survey information will be stored with all of the other information on how you or your child did before, during, and after having the corrective surgery.

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 treatment before, during, or after surgery.Your/your child's surgical and anesthesia management will be exactly the same as it would be if you were not in the study.

The primary risk of this registry is breach of confidentiality. We will take all measures possible to protect the information we collect about your child during the perioperative time period at Boston Children's Hospital. We will keep all information that is on paper in a secure, locked environment. Any information that is kept on the computer will be kept in a secure manner to minimize the chance that anyone could obtain access to the information. All data will be transmitted and stored securely and in an encrypted fashion online through a secured web portal that is password protected. Each site will have access to their local data only. No identifying aspects of your private medical records will be reported to the data coordinating center except for the date of your surgery. This will insure you/your family can not be identified directly by any researchers analyzing all of the data from the participating medical centers at any time. Individual participating sites, including Boston Children's Hospital, will maintain a local master list linking your information in the master database to you. The local master lists will not be shared with any other institutions or the data-coordinating center and will be stored securely and separately at all times.

Although no research studies are planned at this time, in the event future requests for data sets are made, the data-coordinating center Dartmouth Bioinformatics will only prepare and release data sets that have no identifying information allowing anyone to identify you/your family directly.

In spite of our efforts, there is always a chance that some of the information on you or your child's health could be seen by someone not associated with this study. If this happened and we knew about it, you would be informed.

There is always a chance that we may learn of medical findings that may relate either well or badly to you or your child's health and continued well-being, even though we are not studying these events directly. We will let your or your child's doctors in the relevant department involved in providing your or your child's care (e.g., General Surgery or Anesthesia) know about this information within 24 hours of learning of it.

What are the benefits of this research study?

There will be no direct benefit to you/your child from participating in this study. We believe that results of this study may help us improve our quality of perioperative care for patients and families undergoing corrective surgery for PE. This should allow for the development of national safety, quality, and best practice recommendations for medical providers who participate in the medical and surgical care of patients with PE and lead to increased wellbeing and satisfaction among patients and their families undergoing this surgical correction.

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, your child will receive standard clinical care. Refusal to participate will not interfere with you or your child's current or future care received 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 participate or may withdraw from the study at any time without penalty or loss of benefits and without affecting treatment of your child's medical care.

Are there other things I should know about?

At the completion of this study, your child's study data will be given a unique identification number and stored without your child's name. The only identifiable information that we will store will be the date of your or your child's surgery. Only the investigator will have a list to know which information is linked to you or your child and this list will be kept confidential in a secure location.

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.

- You/your child do not complete the questionnaires required for the study.
- 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.

What information do I need to know about the Health Insurance 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.

Contact Information:

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: 617-355-7737 [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]	▪ General questions about the study ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints
Office of	Phone: 617-355-7052	▪ Rights of a research subject

Clinical Investigations	▪ 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 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**