Intrathecal Morphine versus Bilateral Quadratus Lumborum Blocks for Perioperative Analgesia in Pediatric Patients Undergoing Open Lower Abdominal Procedures: A Prospective Randomized Trial

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PROTOCOL TITLE:

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PRINCIPAL INVESTIGATOR:

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- **Objectives / Specific Aims**
  - We hypothesize that intrathecal morphine will have superior analgesia as demonstrated by charted pain scores and morphine equivalents in the first 24 hours.
  - We hypothesize that intrathecal morphine will have higher incidence of side effects when compared to quadratus lumborum blocks

2.0 Background

Postoperatively, abdominal procedures are associated with significant somatosensory pain at the incision site and potential visceral discomfort. Systemic opioid medications were traditionally a critical component for adequate pain control but were also found to be a primary factor contributing to perioperative complications including nausea, vomiting, respiratory depression, and ileus[1].

To reduce systemic opioid administration, regional anesthesia began to play a key role in postoperative pain management for many different types of surgery in children and has done so commonly for at least the last 20 years. A collaborative group of institutions and investigators developed the Pediatric Regional Anesthesia Network to study the practice, risks, and incidence of complications in pediatric regional anesthesia [9]. This group of 21 centers captures data from every regional technique done for children at these hospitals (including neuraxial techniques like spinals, epidurals, and caudals as well as peripheral nerve blocks and peripheral nerve catheters) and has data on over 100,000 pediatric regional blocks. When looking at their database specifically for complications, they found that there were no incidences of permanent neurologic damage, transient neurologic symptoms occurred in 2.4/10,000 blocks, severe local anesthetic toxicity in 0.76/10,000 blocks, and the most common complications were more benign issues like catheter dislodgement leading to block failure (4%)[11]. Comparatively, complications were more common in infants less than 6 months old, and this is consistent with other audits of regional anesthetics done by the French-Language Society of Pediatric Anesthesia, where the overall complication rate was found to be less than 0.1% with more prevalence in the less than 6-month-old population[5]. Further investigations on efficacy of regional anesthesia in pediatric patients has shown decreased need for narcotic pain medications when regional techniques are used. For abdominal surgeries in children, there is no specific standard of care for pain management – just that the anesthetic plan includes a plan for adequate perioperative pain management.

Most abdominal surgeries will have a combination of analgesic modalities with non-steroidal anti-inflammatories and regional anesthesia used to minimize narcotic administration and its associated sedation and side effects. The most common regional techniques used at MUSC for abdominal procedures are intrathecal morphine administration, abdominal wall blocks (including quadratus lumborum blocks), and epidurals. Epidurals also potentially lead to leg weakness (and subsequent patient dissatisfaction) and require increased monitoring at this institution.

Intrathecal morphine has been shown to reduce total opioid consumption for a wide range of pediatric surgical procedures. However, significant rates of pruritis, emesis, and respiratory depression continued to be reported in a dose-dependent manner[2]. Subsequently, low-dose intrathecal morphine (3-5 mcg/kg) was investigated and shown to reduce the incidence of pruritis, emesis, and respiratory depression [1,4]. Fascial plane blocks have also been used for analgesia in abdominal and thoracic procedures in the

pediatric population to improve pain control and reduce postoperative narcotic administration. Quadratus lumborum blocks specifically provide analgesia for the abdominal wall (incisional pain) as well as some visceral pain relief (i.e., pain related to intraabdominal structures). The purpose of this study is to compare the postoperative analgesia provided by intrathecal morphine to that of bilateral quadratus lumborum blocks for open abdominal procedures.

3.0 Intervention to be studied

- Each of the drugs used in this study have been FDA approved for the adult population. Although not approved for pediatric patients, they are commonly used as part of standard practice for pediatric analgesia and well-studied.
- One group of subjects will receive intrathecal morphine: spinal (neuraxial) dose of preservative free morphine (Duramorph), usually about 4-5mcg/kg. This is injected into the cerebrospinal fluid under sterile technique by a pediatric anesthesiologist while the subject is already under general anesthesia. This procedure is well-described in the pediatric population and used regularly for postoperative pain relief for a variety of procedures including open lower abdominal procedures.
- The second group of subjects will have bilateral quadratus lumborum blocks: peripheral nerve block utilizing ropivacaine 0.2%, usually about ½ mL per/ kg per side (total dose approximately 1mL/kg). This is injected in the subject's flank in the fascial plane between the quadratus lumborum muscle and the psoas muscle. Ultrasound guidance is used for needle and structure localization and this procedure is done by a pediatric anesthesiologist while the subject is already under general anesthesia. Quadratus lumborum blocks are regularly used in clinical practice for postoperative pain relief for a variety of open lower abdominal procedures.

4.0 Study Endpoints

- The primary endpoint will compare the effect that intrathecal morphine and quadratus lumborum blocks have on the duration of analgesia as demonstrated by charted pain scores and morphine equivalents in the first 24 hours.
- The secondary endpoint will assess the side effects of each intervention such as nausea and vomiting, and pruritis. Other secondary endpoints will include patient/family satisfaction, sedation, length of hospital stay, length of PACU stay, and analgesia for hospital stay (as approximated at 48 hours).

5.0 Inclusion and Exclusion Criteria/ Study Population

Pediatric patients presenting to undergo ureteral reimplantation surgery will be the study population of interest. Surgery schedules in Epic will be screened for those undergoing this procedure at MUSCs Shawn Jenkins Children's Hospital.

Inclusion Criteria

- Ages 12 months to 11 years old
- Undergoing lower abdominal laparotomy

Exclusion Criteria

- Allergy to morphine or amide local anesthetics
- Localized rash at site of planned regional anesthetic block
- Bleeding diathesis
- Spinal dysmorphism
- Previous spinal surgery with instrumentation of the lumbar spine
- Inability or unwillingness of parent or legal guardian to give informed consent.
- Prior enrollment and randomization in this study

6.0 Number of Subjects

- We will enroll and randomize 30 subjects total.

7.0 Setting

- The study will be conducted at all MUSC preoperative and inpatient locations which includes SJCH, Main (University Hospital), Ashley River Tower, and Rutledge Tower.

8.0 Recruitment Methods

- The study team will refer to the clinic and OR schedules available in Epic to see which patients may qualify. If time allows during the pre-operative clinic visit, the surgeon will briefly introduce the study and provide an informational letter for the patient and family to take home.
- If a potential research subject meets the inclusion criteria, the study team will contact the attending anesthesiologist who will be working the candidate's case to make sure the anesthesia plan does not exclude the patient from the study.
- The patient's parents/guardians will be approached the day of surgery while in pre-op to discuss their willingness to participate in the study.

9.0 Consent Process

Consent will be obtained by IRB approved study team members who have a medical degree and are qualified to discuss the clinical nature of the options being offered.

- As mentioned in the previous section, potential study participants will be informed of the possibility of study participation by their surgeon performing the procedure at the time of discussion of surgery in clinic and be given an informational letter outlining the study. Contact will be made with the child's parent or guardian on the day of the scheduled procedure to discuss the study in greater detail. The study will be explained, and the parent/guardian will be given time to read the consent thoroughly and ask any questions. This will happen in the patient's private room or in the holding area.
- Written informed consent will be obtained if the subject's parent/guardian agrees to participate after the study is thoroughly explained.

- The consent will be obtained in the patient's room or in the private bay in the holding area of MUSC's SJCH.

10.0 Study Design / Methods

- This prospective, randomized, blinded study will attempt to determine if intrathecal morphine provides superior analgesia postoperatively for open lower abdominal procedures when compared to bilateral quadratus lumborum blocks. It will also assess side effects of both pain interventions.
- Once a parent/guardian provide written informed consent, subjects will be assigned a number with a corresponding group. Randomization will be performed by a statistician prior to enrollment and assigned based on the patient's enrollment number. Subjects will be assigned to one of the following groups: 1) Intrathecal Morphine: spinal (neuraxial) dose of preservative free morphine (duramorph), usually about 4-5mcg/kg, or 2) Quadratus Lumborum Block: peripheral nerve block utilizing ropivacaine 0.2%, usually about ½ mL per kg per side (total dose approximately 1mL/kg). The total dose of administered medication (duramorph or ropivacaine) is at the discretion of the anesthesiologist but will be within the dose range as stated above.
- The operating room pharmacist will follow the randomization to prepare or provide the correct medication. Intrathecal morphine will be prepared by the operating room pharmacist. Local anesthetic vials for quadratus lumborum blocks will be obtained from the pharmacy and the medication will be drawn into a syringe by an anesthesiologist who is part of the research team prior to injection. The dosage prepared and administered will be based on weight.
- The pharmacist will not be blinded to the randomization. Nor will the operative team. The study team member who completes data collection from the family and chart review will be blinded to randomization. In addition, the parent and child will also be blinded to the type of block that is used.
- The intervention will be administered in the operating room after the subject is under general anesthesia but prior to incision, as per usual practice. The block will be performed by a study team member board certified in pediatric anesthesiology. Quadratus lumborum blocks are placed using ultrasound guidance, local anesthetic is injected in the fascial plane using aseptic technique. Intrathecal morphine is accomplished by injection of preservative-free morphine in the intrathecal space in the lumbar region using sterile technique.
- Approximately 24 hours after the procedure, a research team member will ask the parent/guardian about side effects such as nausea, vomiting, itching, etc. The research team member will also ask the family if they were satisfied with the subject's pain control postoperatively and overall experience. If a family member or guardian is not present, a care team member will be asked about side effects and the patient's chart will be reviewed for notes pertaining to side effects.
- The patient's chart will be used to see if and how much narcotic pain medication was administered in the first 48 hours after the procedure as well as documented pain scores up to 48 hours after the procedure ends. The chart medication administration record will also be used to identify administration of rescue medications for nausea

or itching non-opioid medications such as acetaminophen or ibuprofen, or other medications such as diazepam or oxybutynin.

Table 1. Baseline and Intraoperative Assessments
Demographics
Baseline
Pre-op meds including opioids in past 24 hours
Randomization
Anesthesia intra-op data
Surgical techniques
Adverse Events

Table 2. Post-Op Follow Up Assessments		
Outcome Measure	**Instrument**	**Collected**
Pain Scores	Charted pain scores	24 and 48 hrs. post-op
Pain Control Satisfaction	Parent/Guardian Satisfaction	24-hours post-op
Side Effects Experienced	Parent/Guardian Satisfaction	24-hours post-op
Overall Satisfaction	Parent/Guardian Satisfaction	24-hours post-op
Opioid Consumption	MME Consumption	24 and 48 hrs. post-op
Side Effects and Adverse Events	Adverse Events	Assessed through post-op hours 0-48
Medications	Medications used to control or relieve side effects	24 and 48 hrs. post-op

12.0 Data Management

- All data will be kept on a password protected MUSC server and in a REDCap database. All paper data sheets will be kept in a locked cabinet, in a locked office that only IRB approved study team members have access to. Participants will be given a study ID number that will be used to identify them throughout the study.
- The primary outcome of interest is duration of analgesia as demonstrated by morphine equivalents per kg of body weight given in the first 24 hours after surgery.
- Secondary outcomes observed include charted pain scores and reported side effects such as nausea/vomiting or pruritis in the first 48 hours as well as patient/family satisfaction, sedation, length of hospital stay, length of PACU stay, and analgesia for hospital stay, the numerical value for SPO2, SPO2 trend, and use or lack thereof of supplemental O2 in PACU in 15-minute intervals for up to two hours after arrival there.

Demographic and clinical characteristics will be described and compared across the two groups using appropriate statistical tests (Chi-squared tests of homogeneity for categorical variables and t-tests for equality of means, etc.). Significant covariables will be assessed for inclusion in modeling. General linear regression methods will be

used to assess the association of post-surgery MMEs with group (QL vs ITM) adjusted for associated covariables.

Our primary hypothesis is that subjects in the two groups with consume different amounts of post-surgery MMEs. Based on preliminary data from a similar study, we assume that MME/kg consumption in the QL block group will be 0.07 ±0.076.

Summary Statements

Assuming a normal underlying distribution, group sample sizes of 12 and 12 achieve 80% power to detect a difference of 0.1 MME/kg between the null hypothesis that both group means are 0.07 and the alternative hypothesis that the mean of group 2 is 0.17 with known group standard deviation of 0.076 and with a significance level (alpha) of 0.05000 using a two-sided Mann-Whitney test. As we anticipate a non-normal distribution, we will inflate sample size by 15%. We will inflate the sample size further by 10% to account for withdrawals.

The final inflated sample size will be 15 per group.

Two-tail test that QL < ITM
H_0= Mean $_{QL}$ = Mean $_{ITM}$
H_a= Mean $_{QL}$ <> Mean $_{ITM}$

13.0 Data Safety Monitoring

- The study will be reviewed annually by the Department of Anesthesia's DSMB. Minutes and outcomes from these meetings will be reported to the IRB as required.
- Adverse events will be recorded and reported to the Department of Anesthesia's Data Safety Monitoring Board and the IRB per policy.
- PHI will be managed in a manner that complies with institutional rules and regulations. There will be an enrollment log that links the study ID number to the patient. This log will be kept on a MUSC password protected server that can only be accessed by IRB approved study personnel.

14.0 Withdrawal of Subjects

- If the anesthesiologist is unable to complete the regional anesthesia administration the patient will be withdrawn from the study.
- If at any time the parent wishes to be withdrawn from the study, then the patient will be withdrawn. This can occur preoperatively or postoperatively when the parent is contacted by the research team approximately 24 hours after surgery. Any data collected prior to withdrawing will be retained.

15.0 Risks to Subjects

- If a parent chooses for their child not to participate, the risk is the same since regional anesthesia is part of standard care at MUSC and will be offered regardless of study participation. Both study medications have been routinely used in practice at MUSC for over ten years.
- Subjects will be assigned to receive intrathecal morphine or a quadratus lumborum block by chance. One group may prove to be less beneficial than the other.
- Intrathecal Duramorph/Morphine: the use is well established in pediatric patients even though it is not FDA approved for use in children, but is commonly used in this population and at this institution for this indication. Other risks include infection at site of injection (less than 1%), damage to surrounding structures (less than 1%), block failure (1%) headache and cerebral spinal fluid leak (7%), Urinary retention (6%), Nausea and vomiting are the most common risks/side effects occurring in less than 10% of patients. Itching occurs in 20-40% of patients. Literature states that patients recover from side effects and are not long term.

  QL Block/Ropivacaine: complications/risks are rare but include local anesthetic systemic toxicity (less than 0.01%), block failure (1%), bleeding and infection at block site (less than 1%), damage to surrounding structures (less than 1%), allergic reaction (rare, less than 1%), neurological complications (less than 1%). Literature states that patients recover from side effects and are not long term.
- There is a risk of loss of confidentiality.

16.0 Potential Benefits to Subjects or Others

- There are no direct benefits to subjects or their families for participation in this study.
- There is a potential benefit that the subject's participation in the study may contribute to knowledge of this area of practice and may impact patient care in the future.

17.0 Sharing of Results with Subjects

- Results will not be shared with participants or their families.

18.0 Drugs or Devices

- The intrathecal morphine will be prepared in the pharmacy by a licensed pharmacist under a sterile hood; the local anesthetic for quadratus lumborum block will be drawn immediately preceding the block from a sterile vial in a sterile operating room by a board-certified pediatric anesthesia attending participating in the study.
- The contents of the injectate will be based off the patient's randomly assigned group.
- The pharmacist will not be blinded to the randomization. Nor will the operative team. The study team member who completes data collection from the family and chart review will be blinded to randomization, as well as the child and parent.
- The drugs used in this study, morphine and ropivacaine, are FDA approved for use in this manner for adults; they have not been FDA approved for children, although they are used regularly as part of standard of care. Intrathecal morphine has been shown to

be safe in pediatric patients for major surgeries. In a recent retrospective study by Keskin et al [6], of 100 children who received 5 mcg/kg intrathecal morphine for major surgery for postoperative analgesia there were no serious adverse events (minor side effects of pruritis and nausea/vomiting seen in small number of patients, 14 and 9 patients respectively). An additional retrospective review from CHOP of 187 pediatric patients concluded that ITM in this population is a useful and safe analgesic adjunct [4]. The usage of intrathecal morphine in pediatric patients undergoing major spinal surgery is well established and without report of major adverse events [7,8]. Ropivacaine use is well established in pediatric patients, whether administered neuraxially (epidural or caudal) or for peripheral nerve block. The European Society of Regional Anesthesia and American Society of Regional Anesthesia published a joint recommendation on local anesthetic use for regional/neuraxial anesthesia in pediatric patients which included dosing strategies for ropivacaine [10].

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Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Intrathecal Morphine versus Bilateral Quadratus Lumborum Blocks for Perioperative Analgesia in Pediatric Patients Undergoing Open Lower Abdominal Procedures: A Prospective Randomized Trial

Your child is being asked to volunteer for a research study because they are undergoing an open lower abdominal procedure. The purpose of this study is to compare two different interventions to help with perioperative pain control. The two interventions are 1) intrathecal morphine or 2) a bilateral quadratus lumborum block. Each of these interventions are commonly used, and safe and effective in children. Your child will be randomly assigned (like the flip of a coin) to which intervention they receive. Neither you nor the study doctor will determine which of the two interventions will be used, nor will you or some members of the study team know which intervention your child receives. Whether or not your child participates in this study, they will be receiving one of the types of anesthesia as it is standard treatment for this procedure.

Intrathecal (spinal) morphine injection occurs after the child is fully asleep under general anesthesia in the operating room. They are placed on their side and their back is cleaned. A needle is inserted into the space containing the cerebral spinal fluid and morphine is injected.

Quadratus lumborum blocks are also placed once fully asleep in the operating room. After cleaning the area, ultrasound guidance is used to advance a needle between the muscle layers of the patient's abdominal wall/side and local anesthetic (numbing medication) is injected.

Approximately 24 hours after your child's surgery, the research team will ask you about your satisfaction with your child's recovery after surgery. The following day the research team will collect information on how much pain medication your child received and any side effect they may have had.

Study participation will start the day of your child's surgery and will end approximately 48 hours later.

The risks of participating include those of the intervention your child is randomized to and loss of confidentiality. Those risks are described in section D of this document. The alternative is for your child to not participate and receive the type of anesthesia their provider chooses.

A. PURPOSE OF THE RESEARCH

Your child is being asked to participate in this research because he or she is scheduled for an open lower abdominal procedure, and a regional anesthetic block is going to be a standard and planned part of their care.
Please read this consent form carefully and take your time making your decision. As your child's study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The investigator in charge of this study at

MUSC is Dr. Natalie Barnett. This study is being done at the Medical University of South Carolina (MUSC). Approximately 30 people will take part in this study at MUSC.

B. PROCEDURES

If you agree for your child to be in this study, the following will happen:

1. Some of your child's demographic and personal information will be collected from their medical record such as age, height, weight, and other information from surgery.

2. Your child will be randomly assigned to one of two groups, like flipping a coin. Neither you, your child, or the researchers will have a choice in which group your child is assigned to. Depending on which group your child is assigned, they will receive one of two types of regional anesthesia 1) intrathecal morphine or 2) quadratus lumbar block. Both interventions are placed once your child is already fully asleep and unaware under general anesthesia. Intrathecal (spinal) morphine injection occurs after the child is fully asleep under general anesthesia in the operating room. They are placed on their side and their back is cleaned. A needle is inserted into the space containing the cerebral spinal fluid and morphine is injected. Quadratus lumborum blocks are also placed once fully asleep in the operating room. After cleaning the area, ultrasound guidance is used to advance a needle between the muscle layers of the patient's abdominal wall/side and local anesthetic (numbing medication) is injected.

3. Approximately 24 hours after your child's surgery ends, someone from the research team will contact you to ask a few questions about your satisfaction of your child's recovery after surgery.

4. We will record what medications are provided up to 48 hours after the surgery is complete, any side effects that occur and how they are treated, as well as additional data recorded in the post-anesthesia recovery unit.

C. DURATION

Participation in the study will take the time in the operating room, post-anesthesia care unit, as well as approximately up to 24 hours after the surgery ends.

D. RISKS AND DISCOMFORTS

Loss of confidentiality: there is a risk of a loss of confidentiality of your child's personal information as a result of participation in this study, but all study team members are trained in the importance of protecting privacy and will do everything possible to minimize this risk. Your child will be assigned a study ID number, which will replace their name on study related documents to further protect their information, and only the research staff will have access to study information.

Randomization: Your child will be randomized to receive one of two treatments. One treatment may prove to be less beneficial than the other.

QL Block/Ropivacaine: complications/risks are rare but include local anesthetic systemic toxicity (less than 0.01%), block failure (1%), bleeding and infection at block site (less than 1%), damage to surrounding structures (less than 1%), allergic reaction (rare, less than 1%), neurological complications (less than 1%). Literature states that patients recover from side effects and are not long term.

Intrathecal Duramorph/Morphine: the use is well established in pediatric patients even though it is not FDA approved for use in children, but is commonly used in this population and at MUSC for this reason. Other risks include infection at site of injection (less than 1%), damage to surrounding structures (less than 1%), block failure (1%) headache and cerebral spinal fluid leak (7%), Urinary retention (6%), Nausea and vomiting are the most common risks/side effects occurring in less than 10% of patients. Itching occurs in 20-40% of patients. Literature states that patients recover from side effects and are not long term.

E. MEDICAL RECORDS AND/OR CERTIFICATE OF CONFIDENTIALITY

Results of research tests or procedures including which type of anesthesia your child received will be included in their MUSC medical record. All information within their medical record can be viewed by individuals authorized to access the record. We will make every effort to keep confidential all research information in the medical record that identify your child to the extent allowed by law.

F. BENEFITS

There is a potential benefit that your child's participation in the study may contribute to knowledge of this area of practice and may impact patient care in the future. Additionally, one treatment may prove to have fewer side effects than the other.

G. COSTS

There will be no additional cost to you for procedures required in this research study. All routine clinical care that you would have undergone without participation in the study, including testing and procedures, will be billed to you/your insurance company.

Some insurance plans will not pay for these services for people taking part in research studies. You will be responsible for any charges that your insurance does not cover including co-payments and deductibles.

H. PAYMENT TO PARTICIPANTS

Your child will not be paid for participating in this study.

I. ALTERNATIVES

The alternative to participating in this study is to not participate. Therefore, your child will instead receive the block that your child's anesthesiologist prefers to use.

J. DATA SHARING

Information about your child (including your identifiable private information) may have all of their identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from your child or their legally authorized representative.

K. DISCLOSURE OF RESULTS

Results will not be shared with your child or your family.

L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your child's study doctor and his/her research team will keep records of their participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:

    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

M. CLINICAL TRIALS.GOV

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Results of this research will be used for the purposes described in this study. This information may be published, but your child will not be identified. Information that is obtained concerning this research that can be identified with your child will remain confidential to the extent possible within State and Federal law. The sponsor and the Food and Drug Administration (FDA) will receive copies of the research records. The investigators associated with this study, employees of the sponsor, the FDA, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that your child is injured as a result of participation in this study, you should immediately take your child to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital and tell the physician on call that your child is in a research study. They will call your child's study doctor who will make arrangements for your child's treatment. If the study sponsor does not pay for your child's treatment, the Medical University Hospital and the physicians who render treatment to your child will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to your child.

Your child's participation in this study is voluntary. Your child may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if your child decides to do this. Your child's decision not to take part in the study will not affect your child's current or future medical care or any benefits to which your child is entitled.

The investigators and/or the sponsor may stop your child's participation in this study at any time if they decide it is in your child's best interest. They may also do this if your child does not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my child's participation in this study or study related injury, I may contact Dr. Natalie Barnett at 843-792-5454. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input about my child's rights as a research subject in this study, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792- 4148. This includes any questions about my rights as a research subject in this study.

I agree for my child to participate in this study. I have been given a copy of this form for my own records.

If you wish to participate, you should sign below.

_____ _____
Signature of Person Obtaining Consent Date *Name of Participant

Participant's Personal Representative (if applicable):

_____
Name of Personal Representative *(Please print)*

_____
Signature of Personal Representative Date

Relationship: ___ Spouse ___ Parent ___Next of Kin ___Legal Guardian* ____ DPOA for Healthcare*

**(If you are the health care agent or guardian, please provide proof of your authority to act on behalf of the patient*