



# CHILDREN'S & WOMEN'S HEALTH CENTRE OF BRITISH COLUMBIA

Department of Anesthesiology  
*British Columbia's Children Hospital*  
4480 Oak Street  
Vancouver  
V6H 3V4  
Tel 604 875 2711  
Fax 604 875 3221

## **PEDIATRIC SUBJECT INFORMATION AND PARENTAL/GUARDIAN CONSENT FORM**

### **Title: Pediatric Caudal Epidural Anesthesia: Ultrasonic Evaluation of Local Anesthetic Spread**

#### **Principal Investigator**

Dr. Gillian Lauder, Dept of Anesthesiology, Pharmacology and Therapeutics, Tel: 604-875-5955

#### **Co- Investigators**

Dr. Mark Ansermino

Dr. Claire Campbell

Joanne Lim

Dept of Anesthesiology, Pharmacology and Therapeutics,

Tel: 604-875-2711

#### **INTRODUCTION**

You are invited to have your child participate in this study because we believe that Caudal Epidural Anesthesia (the injection of drugs, principally local anesthetic, into the lower back) will be the recommended anesthetic for his/her surgery.

#### **YOUR PARTICIPATION IS VOLUNTARY**

Your child's participation is entirely voluntary, so it is up to you to decide whether or not to have your child take part in this study. Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the study, why the research is being done, what will happen to your child during the study and the possible benefits, risks and discomforts.

If you do decide to have your child participate, you will be asked to sign this form. You are still free to withdraw at any time and without giving any reasons for your decision. If you do not wish to have your child participate, you do not have to provide any reason for your decision not to have your child participate nor will your child lose the benefit of any medical care to which they are entitled or are presently receiving. Please take time to read the following information carefully before you decide.

### **WHO IS CONDUCTING THE STUDY?**

The study is being conducted by Dr. Gillian Lauder (Principal Investigator), Dr. Mark Ansermino and Dr. Claire Campbell who are all anesthesiologists working at British Columbia Children's Hospital. The Principal Investigator has not received any financial compensation from any funding agency for enrolling subjects into this study.

### **BACKGROUND**

The anesthesiologist has many ways to help control pain during and after surgery. One such way is to inject anesthetic (pain relieving) drugs into the lower back to prevent the perception of pain. This technique is known as Caudal Epidural Anesthesia (CEA). It is commonly used at this hospital for children undergoing surgical procedures below the bellybutton and considered safe. When CEA is performed, the requirement for other pain relieving drugs called opioid drugs is reduced. Opioid drugs can cause post-operative nausea and vomiting, itchiness, and slower, shallower breathing. Thus, CEA reduces the amount of pain medicines needed that can make your child sick and/or drowsy, allowing a faster recovery time from anesthesia.

Recently, ultrasound has been proposed as a non-invasive means of visualizing accurate needle placement and injection of local anesthetic. Ultrasound is a very safe technology that sends out very high pitch soundwaves that bounce back off muscles, nerves, bones and arteries to give us a clear picture of where these structures are located. Ultrasound imaging of CEA in children allows more accurate needle placement. This alone will improve the safety of the technique. Furthermore, by visualizing the spread of local anesthetic using ultrasound, the use of higher than required volumes can be avoided. This makes the technique even safer and we can be more assured your child will wake up comfortable.

### **WHAT IS THE PURPOSE OF THE STUDY?**

To visualize the spread of a standard dose of local anesthetic injected into the caudal epidural space (lower back). To match the spread of local anesthetic to the variables of age, height, weight, and body surface area with the aim of proposing a new lower, and therefore safer, dosing regime.

### **WHO CAN PARTICIPATE IN THE STUDY?**

Any child from 0 - 2 years of age undergoing routine day surgery below the bellybutton, in whom CEA would normally be used as to provide analgesia (pain relief).

### **WHO CANNOT PARTICIPATE IN THIS STUDY?**

Children who are known to have abnormal anatomy in the lower back region cannot participate in this study.

**WHAT DOES THE STUDY INVOLVE?**

Two anesthesiologists will be present during your child's participation in this study. Once your child is asleep, one anesthesiologist will apply a gel before performing an ultrasound scan of the area to visualize needle placement and anesthetic spread. The ultrasound scan is not invasive and is painless. The other anesthesiologist will perform CEA.

**WHAT ARE YOUR RESPONSIBILITIES?**

To provide consent on your child's behalf.

**WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?**

There may be no direct benefits to you as a result of your child's participation in the study. However ultrasound imaging could identify potential problems, in which case the anesthesiologist performing CEA will be alerted so that amendments can be made at the time of procedure. The information from this study may be beneficial to children receiving CEA in the future.

**WHAT ARE THE RISKS OF TAKING PART IN THIS STUDY**

There is no additional risk associated with participation in this study.

**WHAT HAPPENS IF YOU DECIDE TO WITHDRAW CONSENT TO PARTICIPATE?**

Your child's participation in this research is entirely voluntary. You may withdraw consent for this study at any time without providing any reasons. If you decide to consent to the study and withdraw your child at any time in the future, there will be no penalty or loss of benefits to which you are otherwise entitled.

If you agree to your child entering the study and then decide to withdraw consent at a later time, all data collected in the study will be retained for analysis. By law, this data cannot be destroyed.

**WHAT HAPPENS IF SOMETHING GOES WRONG?**

In the unlikely event that something goes wrong emergency medical services will be obtained promptly. The ultrasound machines used are commercially available and therefore have already undergone safety testing. If there is any concern about the safety of the ultrasound equipment then scanning will not commence or be stopped immediately. If there is any change in the condition of your child then scanning will be immediately stopped.

By signing this consent form neither you nor your child are waiving your or your child's legal rights or releasing the investigator from their legal and professional responsibilities

**WHAT WILL THE STUDY COST?**

There will be no cost to you for your participation in the study, nor will there be any remuneration or reward for taking part.

**WILL YOUR CHILD'S PARTICIPATION IN THIS STUDY BE KEPT CONFIDENTIAL?**

Confidentiality will be respected. No information that discloses you or your child's identity will be released or published without your specific consent to the disclosure. However, research records identifying you and your child may be inspected in the presence of the Investigator or his or her designate by representatives of Health Canada and the UBC Research Ethics Board for the purpose of monitoring the research. However, records which identify you and your child by name, initials or date of birth will be kept in a locked cabinet and will not be allowed to leave the Investigators' offices. Copies of relevant data, which identify you and your child only by code number may be required by the regulatory agencies or viewed by other collaborators or industry partners in comparing different methods. However, you and your child will not be identified by name, initials, or date of birth as part of this study data.

In reporting results from this study, we will not identify you or your child.

**WHO TO CONTACT IF YOU HAVE QUESTIONS ABOUT THE STUDY DURING YOUR PARTICIPATION?**

If you have any questions or desire further information about this study before or during your participation, contact Dr. Gillian Lauder at 604-875-5955.

**WHO DO YOU CONTACT IF YOU HAVE ANY QUESTIONS OR CONCERNS ABOUT YOUR RIGHTS AS A SUBJECT DURING THE STUDY?**

If you have any concerns about your rights and/or experiences as a research subject, please contact the Research Subject Information Line at the University of British Columbia, Office of Research Services, at 604-822-8598.

## CONSENT TO PARTICIPATE

I have read all of the above. I have had enough time to consider entry to the study. All of my questions have been answered to my satisfaction. I understand that my child's participation is entirely voluntary and that I may refuse participation, or may withdraw from the study at any time.

I will receive a signed and dated copy of this consent form for my own records.

I do not waive any of my legal rights by signing this consent form.

The parent(s)/guardian(s) and the investigator are satisfied that the information contained in this consent form was explained to the child to the extent that he/she is able to understand it, that all questions have been answered, and that the child assents to participating in the research.

---

Printed name of Parent/Guardian	Signature	Date
---------------------------------	-----------	------

---

Printed name of witness	Signature	Date
-------------------------	-----------	------

---

Printed name of principal investigator/ designated representative	Signature	Date
--	-----------	------