UNIVERSITY OF ALBERTA

FACULTY OF MEDICINE & DENTISTRY
DEPARTMENT OF PEDIATRICS

# PARENT/GUARDIAN CONSENT FORM

**Title of Study:** A Study of Non-Steroidal or Opioid Analgesia Use for Children with Musculoskeletal Injuries

**Principal Investigator:** Dr. Samina Ali (780) 248-5574
**Research Coordinator:** Ms. Manasi Rajagopal (780) 248-5440

**Why am I being asked to consider this research study?**
You are being asked if you and your child would like to be part of a research study. In this study, we are trying to determine the best ways to treat children's pain due to a limb injury. You are being asked to take part as your child may have pain due to an injury and is between 6 and 17 years old.

Before you make your decision one of the research team members will review this form with you. A copy of this sheet will be given to you to keep. If you would like more information, please feel free to ask. You are encouraged to ask questions if you feel anything needs to be made clearer. Please take the time to read this document carefully.

If your child is old enough to understand this information we would also like you to talk to them about being part of the study. If your child is 7 years of age or older, we would like you both to sign a form if you would like to participate in the study.

**What is the reason for doing the study?**
The purpose of this research study is to figure out which of three pain medicines best treats a child's pain. The pain medicines we are studying are ibuprofen (Advil/Motrin), acetaminophen (Tylenol/Tempra), and hydromorphone (Dilaudid). Ibuprofen and acetaminophen are the top two medicines used in the world and are approved for children's pain in Canada. Hydromorphone is used and approved for treating many kinds of children's pain in Canada, and we have received Health Canada approval to study it for the pain of limb injuries, since Canada has not yet approved it specifically for this problem. This study will help us figure out which pain medicine or combination of pain medicines works best for children with limb injuries. We would also like to understand the thoughts and feelings you have when making decisions about pain medication for your child.

This study is being conducted in six children's hospitals across Canada, and we will ask a total of over 500 children to be part of this study. Approximately 100 of these children will be recruited from the Stollery Emergency Department.

**What will happen in the study?**
If you agree to take part in this study, we will ask you to select which one of our two study groups you would like to be enrolled in: Group 1 OR Group 2. Regardless of which study you choose, your child will, at minimum, receive ibuprofen (Advil/Motrin) for their pain.

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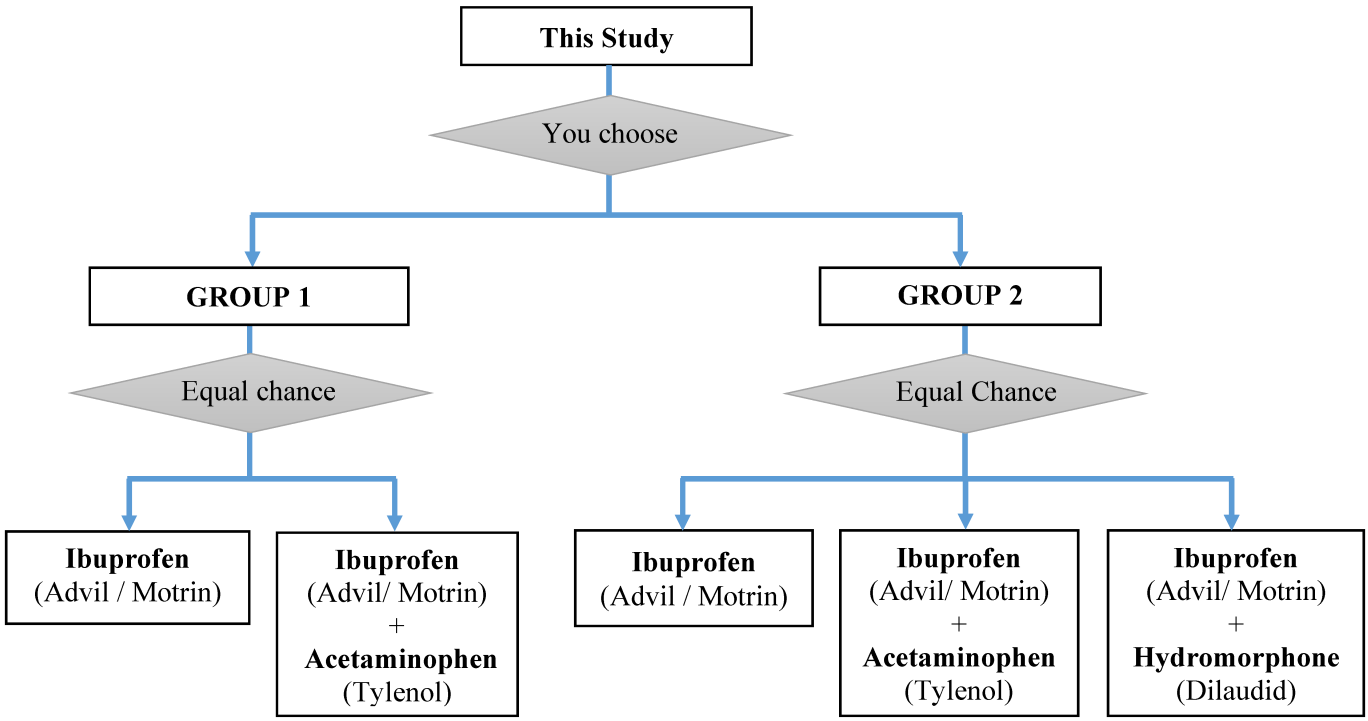
If you select **Group 1**, your child will have an equal chance of receiving one of the two medicine options below. This will be decided by the computer at random, so there is an equal chance of receiving either option, like the toss of a coin.

1. Oral liquid Ibuprofen (Advil/Motrin) only OR
2. Oral liquid Ibuprofen (Advil/Motrin) and oral liquid acetaminophen (Tylenol/Tempra)

If you select **Group 2**, your child will have an equal chance of receiving one of the following three medicine options:

1. Oral liquid Ibuprofen only (Advil/Motrin) OR
2. Oral liquid Ibuprofen (Advil/Motrin) and oral liquid acetaminophen (Tylenol/Tempra) OR
3. Oral liquid Ibuprofen (Advil/Motrin) and oral liquid hydromorphone (Dilaudid)

If you don't have a preference for a study group, we will assign you to Group 2, as this group includes all three of the options you might be offered when participating in this research study.




All children in the study will receive ibuprofen (Advil/Motrin), which is the standard medicine given to children for injury-related pain. Some children will also receive either acetaminophen (Tylenol/Tempra) or hydromorphone (Dilaudid). Neither the study nurse nor your doctor will know which combination of medicines your child has received for the study, but if we need to know this for medical reasons we can find out. After the study medicines have been given, your child may also get further medicines, which are not part of the study, as routinely recommended by the emergency doctor who is taking care of your child.

During the study your child will be monitored closely by the study nurse. The study nurse will measure your child's heart rate, breathing rate, blood pressure, oxygen levels, and pain levels every 30 minutes for up to 2 hours. They will also measure your child's pain when the doctor examines him/her and immediately following any X-ray procedures. If your child's medical care is finished before the 2-hour study period, and you are ready to leave, this is not a problem. Our research nurse will collect the measurements from your child one last time, and then you can go home, at your will. Participating in this study should NOT delay your leaving the emergency department or affect the timing of when the doctor will see you.

We will ask you to complete a short 5-minute questionnaire on an iPad, while you are in the emergency department today. This questionnaire will ask about your demographics, your child's injury and about your reasons for choosing your study group (ie. Group 1 vs. Group 2). We will also complete two 5-10 minute follow up surveys to see how your child is doing. You will have the option of completing these by email (we will send you a link through a secure online portal called REDCap) or over the phone. The survey will be done 24 hours after you leave the emergency department, and again 1 week after. After the two surveys are done, your part of this study is done.

**What are the risks and discomforts?**
Your child may experience side effects from participating in this study. Some side effects are known and listed below, but there may be risks in this study that are currently not known. If we find out anything new during the course of this study that may change your willingness to be in the study, we will tell you about these findings.

Based on our team's previous work, we expect nausea, mild dizziness, and tiredness to be possible non-serious common side effects. It is possible that your child might experience this. There is a very rare risk of serious drowsiness and low breathing rate following the use of any opioid medicine; this is extremely rare when the medicine is taken by mouth, like it is in this study. Even though such events are very rare, we want to make sure that your child is safe at all times. So, our research nurse will be watching your child closely for these effects and will even use an oxygen monitor to closely observe them. If such an event were to occur, the emergency team of doctors and nurses would take care of your child, as they are already present in the department.

Finally, there is an extremely rare risk of an allergic reaction to one of the study medicines.

**What are the benefits to my child?**
Your child may not benefit directly from being in the study, but you will be helping us understand how to best treat pain in children who come to the emergency department.

**What happens if my child is injured because of this research?**
If your child becomes ill or injured as a result of being in this study, he/she will receive necessary medical treatment, at no additional cost to you. By signing this consent form you are not releasing the investigator(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities. Contact the principal investigator, Dr. Samina Ali, at 780-248-5574, if your child has suffered an injury. If required, go to the emergency department right away.

**Do I have to take part in the study?**
Being in this study is your and your child's choice. If you decide to be in the study, you can change your mind and stop being in the study at any time by letting the research nurse know. This will in no way affect the care or treatment that your child is entitled to.

**Can our participation in the study end early?**
In addition to you being able to stop the study at any time, the study doctor may withdraw your child from this study for reasons such as:

- Your child is unable to tolerate the study medication
- The study doctor no longer feels this is the best option for your child

If your child is removed from this study, the research team will discuss the reasons with you and plans will be made for your child's continued care outside of the study.

**Are there other choices to being in this research study?**
If you choose not to take part in this study today, your child's doctors and nurses will decide what medicines to treat your child's pain with.

**What will it cost me to participate?**
There will be no costs to you to be in this study.

**Will my information be kept private?**
During the study, we will be collecting health data about your child. We will do everything we can to make sure that this data is kept private. No data relating to this study that includes your child's name will be released outside of the study doctor's office or published by the researchers. Sometimes, by law, we may have to release your information with your name in it so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your health information is kept private.

The study doctor/study staff will look at your child's personal health records held at the hospital, and/or kept by other health care providers that your child may have seen in the past (i.e. your family doctor). Any personal health information that we get from these records will be only what is needed for the study.

During research studies, it is important that the data we get is accurate. For this reason, your child's health data, including their name, may be looked at by people from: the research team, the study sponsor (University of Alberta), the University of Alberta auditors, clinical trial monitors, and Research Ethics Board, and Health Canada. By signing this consent form you are giving permission for the study doctor/staff to collect, use and disclose information about your child from his/her personal health records, as described above.

After the study is done, we will still need to securely store your health data that was collected as part of the study. In Canada, the law says we have to keep the data stored for 25 years after the end of the study. The data we collect will be stored, in Canada, on a system called REDCap. It will be accessible to and managed by, staff at the Women & Children's Health Research Institute

at the University of Alberta. If you leave the study, we will not collect new health information about you, but we will need to keep the data that we have already collected.

After study completion, your study data may be used again by other researchers. Any of your personal information (i.e. your name, address, telephone number) that can identify you will be removed or changed before files are shared with other researchers. Researchers that wish to use study data must 1) have their new study approved by an ethics board; 2) sign an agreement ensuring your confidentiality and restricting data use to only the approved study.

**What if I have questions?**
If you have any questions about the research now or later, please contact the principal investigator Dr. Samina Ali at 780 248 5574, or the research coordinator Ms. Manasi Rajagopal at 780 248 5440.

If you have any questions regarding your rights as a research participant, you may contact the Health Research Ethics Board at 780-492-2615. This office is independent of the study investigators.

A copy of this sheet will be given to you to keep. This study is funded by the Canadian Institutes of Health Research and the Women and Children's Health Research Institute. The Institution and study doctor are getting money from the study sponsor to cover the costs of doing this study. You are entitled to request any details concerning this compensation from the Principal Investigator.

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## CONSENT

**Title of Study:** A Study of Non-Steroidal or Opioid Analgesia Use for Children with Musculoskeletal Injuries

**Principal Investigator(s):** Dr. Samina Ali **Phone Number:** 780 248 5574
**Research Coordinator:** Ms. Manasi Rajagopal **Phone Number:** 780 248 5440

| | Yes | No |
|---|---|---|
| Do you understand that you and your child have been asked to be in a research study? | ☐ | ☐ |
| Have you read and received a copy of the attached Information Sheet? | ☐ | ☐ |
| Do you understand the benefits and risks involved in taking part in this research study? | ☐ | ☐ |
| Have you had an opportunity to ask questions and discuss this study? | ☐ | ☐ |
| Do you understand that you and your child are free to leave the study at any time, without having to give a reason and without affecting your child's future medical care? | ☐ | ☐ |
| Has the issue of confidentiality been explained to you? | ☐ | ☐ |
| Do you understand who will have access to your child's records, including personally identifiable health information? | ☐ | ☐ |

Who explained this study to you? _____

I agree for my child and I to take part in this study, and I have the legal authority to give this consent.

Signature of Parent or Guardian _____

(Printed Name) _____

Date: _____ Time: _____: _____ AM / PM
(circle one)

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Signature of Investigator or Designee _____

Date: _____ Time: _____: _____ (24h clock)
(dd / mmm / yyyy)

**THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A SIGNED COPY GIVEN TO THE RESEARCH PARTICIPANT**

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**CHILD ASSENT FORM**

**Title of Study:** A Study of Non-Steroidal or Opioid Analgesia Use for Children with Musculoskeletal Injuries: The No OUCH Trials

**Principal Investigator:** Dr. Samina Ali **Phone Number:** (780) 248-5574

**Study Coordinator:** Ms. Manasi Rajagopal **Phone Number:** (780) 248-5440

We want to tell you about a research study we are doing. A research study is a way to learn new information about something. Children do not need to be in a research study if they don't want to.

**Why am I being asked to be in this study?**

We would like to find out more about what pain medicine works best for children with sprains or broken bones. You are being asked to join the study because you have pain due to an injury. Over 500 kids will take part in this study.

**If I join the study, what will I have to do?**

If you and your parent agree to take part, we will ask you to do a few things:

- First, we will ask you to take some pain medicines.
- Then, we will ask you to tell us about your pain, how you are feeling, and if you have any bad effects from the medicines we gave you.
- While you are in the emergency department, we will also check your heart rate and breathing.
- After you leave here, we will call or email your parents tomorrow and again after 1 week, to see how you are doing.

**Will any part of the study hurt?**

No, but sometimes kids can feel a little bit tired or sleepy after taking pain medicine. It is possible that you might feel this, but your parents and the research nurse will be there to help you, if this happens.

**Will the study help me?**

If you take part in this study, we hope the medicine we give you will help you. Even if you don't take part in the study, you can still ask your nurse for pain medicine, if you need it.

**Will the study help others?**

This study will help us figure out the best way to take care of kids' pain in the future.

**What do I get for being in this study?**

There are no direct cash or gifts for you for helping with this study.

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**Can I say no?**
Yes, of course, you do not have to be in the study. It's up to you. If you do join the study, you can change your mind and stop being part of it at any time. No one will upset if you decide you don't want to do this study or if you decide to stop part way through. You can tell your parents, your doctor or the research nurse if you want to quit. Before you say **yes or no** to being in this study, the research nurse will answer any questions you have. If you join the study, you can ask questions at any time.

**What other choices do I have if I say no to this study?**
If you choose not to be this study, your doctor and nurse will decide what pain medicines to give you. The three medicines that we are using in this study are the most commonly used medicines for this type of injury.

**Do my parents know about this study?**
This study was explained to your parents and they said that we could ask you if you want to be in it. You can talk this over with them before you decide.

**Who will see information about me?**
The information collected about you during this study will be kept safe. Nobody will know it except the people doing the research. The study information about you will NOT be given to your friends or teachers or anybody else.

**What if I have any questions?**
You can ask your mom or dad about anything you don't understand. You can also talk to the research nurse who is here, today. Dr. Samina Ali is the main doctor in charge of this study. If you have any questions about this study that you didn't think of now, either you can call or have your parents call her at 780 248 5574. You will be given a copy of this paper to keep.

**Would you like to take part in this study?**

☐ **Yes, I will be in this research study.** ☐ **No, I don't want to do this.**

| _____ | _____ | _____ | _____ : _____ am / pm |
|---|---|---|---|
| Child's Name | Signature of Child | Date | (circle one) |

☐ Assent was obtained verbally Age at the time of assent: _____ years

| _____ | _____ | _____ | _____ : _____ |
|---|---|---|---|
| Person obtaining Assent | Signature | Date (dd/ mmm/yyyy) | (24h clock) |