Supplementary Online Content


eAppendix 1. Group 8 describes a short consent document written at 8th grade reading level with high processability and inclusion of risk/benefit graphics.

eAppendix 2. Group 10 describes a longer consent document written at 12th grade reading level with low processability and no graphic depictions of risks and benefits.

This supplementary material has been provided by the authors to give readers additional information about their work.
GROUP 8 CONSENT DOCUMENT

UNIVERSITY OF MICHIGAN - CONSENT TO BE IN RESEARCH

INFORMATION ABOUT THIS FORM

Your child may be able to take part in a research study.

This is voluntary and your child does not have to take part.

This form tells you about the study. Please take time to read the form, and talk about it with others.

Please do not sign this form until you get your questions answered and you understand the information.

ABOUT THIS STUDY

Dosing and Safety of Switching from Short-Acting to Long-Acting Painaway in Children

Sponsor: SCiFi. Pharma

Researchers: J. Doe, M.D., S. Smith, M.D., B. Brown, M.D

Department of Anesthesiology

PURPOSE

This is a study about treating pain in children.

Painaway is a pain reliever similar to morphine, used to treat medium to severe pain in children who can take medicine by mouth.

There are 2 forms of Painaway:

- Painaway-IR (Immediate release or Short-acting) – given every 4-6 hours
- Painaway-CR (Controlled release or Long-acting) - given every 12 hours

This study will:

- Evaluate the safety of changing from the short- to long-acting form of Painaway
- Evaluate how much Painaway gets in the blood and how good it is in reducing pain in children

WHO CAN TAKE PART IN THE STUDY?

100 children aged 6 - 16 yrs who need medicine for medium to severe pain can take part

WHAT WILL HAPPEN DURING THE STUDY? (PROCEDURES)

Children in the study will:

1) Get Painaway for pain relief

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The following table shows what will happen during the study:

### Before we start we will:
- Obtain information about your child (medical history and current medicines)
- Measure Vital Signs (blood pressure, heart rate, etc.), oxygen level
- Do a brief physical exam
- Obtain blood sample (from IV, if present)

### During the study (when the child is ready for medicine by mouth):

#### Pain medicine:
- Painaway-IR (short-acting) will be given every 6 hrs for 1 day followed by: Painaway-CR (long-acting) two times a day for 2 days
- Other pain medicines can be given if Painaway is not working well

#### Assessments:
- We will measure Vital Signs, check for sleepiness and oxygen level, and ask your child about their pain level
- Up to 5 small blood samples will be taken each day during the first 2-3 days
- We will also check for side effects each day

### End of Early Study (Day 3)
- Physical exam and Vital Signs
- Blood sample
- Check for side effects

### Long-term Study (for children who need ongoing pain medicine - up to 3 months)
- Painaway-CR given twice a day
- Doctor visit once a month
- Physical exam, Vital signs, and Blood Sample at very end of study (3 months or earlier)

### How long the study lasts
Your child’s part in this study will last from 3 days to 3 months, based on whether your child needs to stay on the medicine after leaving the hospital.

*More details about the study drug doses and blood tests are available if you’d like them.*

<table>
<thead>
<tr>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
</tr>
</thead>
</table>

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## Pain Medicine

<table>
<thead>
<tr>
<th>Short-Acting</th>
<th>Long-Acting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Painaway-IR</td>
<td>Painaway-CR</td>
</tr>
</tbody>
</table>

**Given**
- **Painaway-IR (short-acting)**: Given every 6 hours X 4-5 doses
- **Painaway-CR (long-acting)**: Given every 12 hours

*May still use morphine or other pain treatment as needed*

### Assessments

<table>
<thead>
<tr>
<th>Pain scores</th>
<th>Pain scores</th>
<th>Pain scores</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vital signs</td>
<td>Vital signs</td>
<td>Vital signs</td>
</tr>
<tr>
<td>Oxygen saturation</td>
<td>Oxygen saturation</td>
<td>Oxygen saturation</td>
</tr>
</tbody>
</table>

### Blood Samples

<table>
<thead>
<tr>
<th>Up to 5 samples over day</th>
<th>Up to 5 samples over day</th>
<th>Up to 5 samples over day</th>
</tr>
</thead>
</table>

## WHAT ARE THE RISKS OF THE STUDY?

The risks for Painaway are **similar to other morphine-like drugs**.

About **30 out of 100 children (30%)** may experience these common side effects:

- **Light-headedness or dizziness**
- **Nausea and vomiting**
- **Constipation**

Less than **3 out of 100 children (3%)** may experience these effects:

- **Excessive sleepiness (sedation)**
- **Slowed breathing**

**Children who cannot swallow pills should NOT be in the study**, since Painaway-CR tablets must be swallowed whole. **If these pills are broken, chewed, or crushed they are dangerous.**

- Allergic reaction is possible with any drug, and will be watched for.

- **Risks of taking blood are low and include the pain from a needle stick and/or bruising.** Blood samples will be taken from an IV line if possible to avoid these effects.

### Table 2. Possible Side-effects of Painaway

<table>
<thead>
<tr>
<th>Side-effects</th>
<th>Prevention or Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Common effects that may occur in 30 out of 100 children (30%)</strong></td>
<td></td>
</tr>
<tr>
<td>Light-headedness or dizziness</td>
<td>Adequate hydration</td>
</tr>
<tr>
<td>Nausea and vomiting</td>
<td>Rest</td>
</tr>
<tr>
<td>Constipation</td>
<td>Medicines for nausea</td>
</tr>
<tr>
<td></td>
<td>Stool softeners or laxatives</td>
</tr>
</tbody>
</table>
**Rare, but potentially serious effects may occur in less than 3 out of 100 children (3%)**

<table>
<thead>
<tr>
<th>Effect</th>
<th>Prevention/Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excessive Sleepiness</td>
<td>Careful monitoring</td>
</tr>
<tr>
<td>Slowed breathing</td>
<td>Lowering the dose of Painaway</td>
</tr>
<tr>
<td></td>
<td>Medicine to reverse Painaway</td>
</tr>
<tr>
<td></td>
<td>Oxygen</td>
</tr>
</tbody>
</table>

**Other possible risks of the study**

<table>
<thead>
<tr>
<th>Risk</th>
<th>Prevention/Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allergic reaction</td>
<td>Stopping the Painaway if reaction occurs</td>
</tr>
<tr>
<td></td>
<td>Anti-histamines</td>
</tr>
<tr>
<td>Unknown risk to fetus</td>
<td>Negative pregnancy test is necessary</td>
</tr>
<tr>
<td>Risks that are unknown at this time</td>
<td>Tell the doctors or nurses if your child has any problems</td>
</tr>
<tr>
<td>Pain or bruising from blood draws</td>
<td>Blood will be taken from IV lines whenever possible</td>
</tr>
</tbody>
</table>

**Your child should not participate if he/she cannot swallow pills or tablets since broken, chewed or crushed tablets may be dangerous**

**Pregnancy Risk:**

This study may involve risks to unborn children, so girls who have started their period must have a negative pregnancy test to take part.

**Unknown side-effects may occur.** If new information becomes known while your child is in the study, we will let you know.

Please tell the researchers about any side effects or other problems that your child has during this study. You should also tell your child’s regular doctors.
Can my child take part in other studies if he/she is in this one?

Your child **should not take part in more than one study** without approval from the study team.

**WHAT ARE THE BENEFITS OF THE STUDY?**

♫ Your child will receive medicine that may relieve pain and he/she will be able to take other pain medicines if needed.

♫ Studies suggest that **75 out of 100 patients (75%) who receive Painaway will have good pain relief.**

♫ Your child’s part will help us **learn about how to best manage pain in children who may need Painaway for medium to severe pain.**

**Table 3. Possible Benefits of the Study**

75 out 100 Children (75%) will get good pain relief

Your child’s part will help us learn about how to best manage pain in children who may need Painaway for medium to severe pain

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**OTHER OPTIONS TO THIS STUDY**

If your child does **not** take part in this study, he/she will **receive standard care.**

- The **same or different pain medicines will be given.**

- **Some of the same assessments** (e.g. Vital Signs and oxygen level) may be done, but **no extra blood testing**, apart from routine care, will be done.

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**ENDING THE STUDY EARLY**

- **Your child can leave the study at any time** by telling the study team.
- If your child leaves the study early be sure to follow doctor’s orders about treating pain since stopping pain medicine quickly may cause bad effects.

Your child may be taken out of the study early if:
- Your child’s condition changes and it is no longer good to stay in the study
- You or your child cannot follow study orders
- The study is stopped

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**FINANCIAL INFORMATION**

- There are no added costs to you or your insurance carrier.
- SCiFi Pharma will cover all costs and will pay for all study medicines

😊 You will receive a $5.00 gift certificate at the end of the study.

- SCiFi Pharma could profit from the study results

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**PRIVACY**

- All study information will be kept in our research records in the locked offices of the study team and will be protected by our privacy policies.
- Only people in the study can see these records.
- Your child’s name will not be put into any of the research records, but will be kept apart from those records so that we can review medical information, if necessary.
- The study team will get to see your child’s private health information. (Study team includes the nurses and doctors doing the study, company monitors, and sometimes officers from the FDA.)
- Your child will not be identified in any publications that come from this research.

For more information about privacy, ask for a copy of the University of Michigan Notice of Privacy Practices. This information is also available on the web at [http://www.med.umich.edu/hipaa/npp.htm](http://www.med.umich.edu/hipaa/npp.htm).

---

**STUDY CONTACTS**

Principal Investigator: Dr. J Doe
Study Coordinator:
Mailing Address:
Telephone:

If you have any concerns, you may also contact:
# SIGNATURES

**YOUR SIGNATURE BELOW MEANS:**

I understand the information printed on this form.

I have discussed the study, its risks, benefits, and other choices with ______________________.

My questions so far have been answered.

I understand that I will receive a copy of this form at the time I sign it and that one will be kept in the research files and possibly my child’s medical record.

Name of child (Print legal name):__________________________________________

Patient ID: __________________________ Date of Birth: _____________________

**Parent or guardian:**

Name (Print legal name): __________________________

Signature __________________________ Date: __________________

Check Relationship to Subject:

☐Parent  ☐Legal Guardian  ☐Other:

**Principal Investigator (or Designee):**

I have given this research subject (or his/her legally authorized representative, if applicable) information about this study that I believe is accurate and complete. The subject has indicated that he or she understands the nature of the study and the risks and benefits of participating.

Name: __________________________ Title: __________________________

Signature: __________________________ Date of Signature: __________________________
Your child may be eligible to take part in a research study. This form gives you important information about the study, describing the purpose of the study, as well as the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to discuss the project and your child’s potential participation in this study with others (for example, your friends, family, or other doctors). If you decide to have your child participate in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title: A Multicenter, Open-Label, Multiple-Dose Study of the Conversion From Immediate Release Painaway to Controlled Release Painaway to Evaluate Pharmacokinetics and to Characterize Safety and Efficacy in Pediatric Patients 6 to ≤ 16 Yrs of Age.

1.2 Company or agency sponsoring the study: SCiFi. Pharma.

1.3 Names, degrees, and affiliations of the researchers conducting the study:
J. Doe, M.D., S. Smith, M.D., B. Brown, M.D.
Department of Anesthesiology

2. PURPOSE OF THIS STUDY

2.1 Study purpose: You are being asked permission for your child to participate in a research study for managing pain in children. Painaway (Painaway-IR; Painaway immediate release) is an opioid analgesic with similar effects as morphine, however, it is much better absorbed when administered orally. In the US, Painaway is available as an immediate release product in an oral solution, a capsule, and combined with acetaminophen or aspirin. In the immediate release form, it must be given approximately every 6 hours. The controlled-release form of Painaway (Painaway-CR; Painaway controlled release) only needs to be administered every 12 hours. Painaway is prescribed for patients with moderate to severe pain who need around-the-clock pain relief. Much of the basic information about choosing the right formulation of Painaway is known only for adults. The safety, efficacy and dosing information of the two Painaway formulations have not been approved by the US Food and Drug Administration (FDA) in pediatric patients because clinical studies have not been done in this group. Additional information will help doctors develop better dosing guidelines for pediatric patients.

The main purpose of this study is to evaluate the safety of the conversion from the short acting form of the pain medicine Painaway (i.e., Painaway-IR), to a longer acting controlled release form of the same pain medicine (i.e., Painaway-CR).

Another purpose of the study is to evaluate the pharmacokinetics (PK) (laboratory testing to measure the amount of Painaway in your child’s blood) of both Painaway-IR and Painaway-CR in children.

This study will also evaluate the pain relieving qualities of Painaway, both in its immediate release form, and when switching to the controlled release form when it is given to pediatric patients.
3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Participating in this study is completely voluntary. Your child does not have to participate if you don't want him/her to. You and your child may also withdraw from the study at any time, even before it is finished. If your child leaves the study before it is finished, there will be no penalty to you or your child, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?
Children between the ages of 6 and 16 years who are hospitalized, receiving around-the-clock morphine or another similar pain medicine for the treatment of moderate to severe pain that is expected to last for 3 weeks or longer are eligible.

3.2 How many people (subjects) are expected to take part in this study?
Approximately 100 pediatric subjects from approximately 30 hospitals within the United States, Canada, and Europe will participate in this study. Approximately, 40 subjects will be 6 to less than 12 years of age and approximately 60 subjects will be 12 to 16 years of age.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to my child in this study?
Children in this study will have Painaway administered for his/her analgesia, will also receive extra monitoring, and will need to have extra blood draws as outlined below.

Pre-study:
Before starting the study drug, the following things need to be done to decide whether your child qualifies to participate. You will be asked questions about your child’s medical history, and current medicines. A complete physical examination will be performed, and measurements of vital signs (breathing rate, pulse rate and blood pressure) and temperature will be taken. A blood sample will be collected from an existing intravenous (IV) or arterial line whenever possible, to conduct routine laboratory tests. In some cases, a needle stick to draw blood from a vein will be necessary. If applicable, a pregnancy test for females of childbearing potential will be performed.

During treatment:
Before the first dose of study medication, your child’s vital signs and oxygen saturation (level of oxygen in the blood measured with a device that shines light through your finger) will be measured. We will also ask your child to rate how much pain he/she feels right now.

Study Dosing Schedule:
If your child is recovering from surgery, study treatment will begin when he/she is ready to take medication orally. If your child has not had surgery he/she will start study treatment when your doctor decides it is appropriate. When your child is able to start taking pain medicine orally, his/her current analgesic therapy will be discontinued and he/she will begin taking Painaway-IR capsules orally every 6 hours for either 4 or 5 doses, depending on the time of day the first dose is given. Your doctor will prescribe the amount of Painaway-IR, as appropriate, based on how much pain medicine your child required over the last twenty-four hours. Depending on how your child responds after the first dose, the second dose of Painaway-IR may be either increased or decreased by your doctor. The remainder of your child’s doses will be the same as the second dose. After the first day, your child’s pain medication will be converted to Painaway-CR by mouth every 12 hours for up to 4 doses. When the conversion from immediate to controlled-release is made, the total dose of pain medicine will not change, only the number of doses will change (i.e., the number of doses will decrease).
If your child requires additional analgesic medication, your child will be allowed to receive morphine, either with a PCA pump (a Patient Controlled Analgesic administered intravenously) or in an oral liquid form until comfortable. If your child is unable to take morphine, then your doctor will prescribe another opioid analgesic other than Painaway.

After the study is completed, your child’s pain medication will be prescribed by the doctor based on your child’s need and the doctor’s usual practice.

**Blood Sample Collection:**
A small blood sample (2.5mL or about ½ teaspoon) will be collected for routine laboratory testing at three different times, once before treatment, at the end of 3 days, and again at the end of the study.

Blood samples will also be collected at scheduled times over the first 3 days of the research study to measure the level of Painaway in your child’s blood. After some doses, as many as 4 samples will be taken during the next 6 to 12 hours, and after other doses, there will be no samples taken. If one is not already present, an intravenous (IV) catheter (a very small tube that allows blood to be collected) will be inserted in a vein so he/she will not need a needle stick for each sample taken. The total amount of blood collected at the scheduled time intervals will be 24 mL or approximately 5 teaspoons.

**Study Assessments:**
Throughout the first 3 days of the study, the doctors and nurses will visit your child to assess how sleepy he/she is and to ask them to rate how much pain they are having. The care providers will also measure vital signs including blood pressure, breathing rate, heart rate, and the level of oxygen in his/her blood. After your child’s fourth dose of Painaway-CR the same measurements will be repeated, and a complete physical examination will be performed. A blood sample will be collected for routine laboratory tests. If your child has tolerated the medicine well, he/she will be continued on Painaway-CR twice a day for as long as he/she needs the medicine or for up to 3 months, whichever comes first.

**Long-term phase:** Once your child has been discharged from the hospital, he/she will be asked to come for a visit at the doctor’s office once every month while taking Painaway-CR. You will bring his/her medication bottle to the doctor’s office at each visit. The study doctor will ask if he/she has had any problems and will check vital signs and temperature. At the conclusion of the visit the doctor will supply you with the medication for the following month. At your child’s final visit a complete physical examination will be performed, a measurement of your child’s vital signs and temperature will be recorded, and if agreed, a final blood sample will be collected for routine laboratory tests.

**4.2 How much of my child’s time will be needed to take part in this study?**
Your child’s participation in this study will last from 3 days to 3 months. The first part of the study will take place in the hospital, and is planned to last for up to 3 days. Children who need the pain medicine for a longer period of time can participate in the study for up to 3 months.

**4.3 When will my child’s participation in the study be over?**
Your child’s participation in the study will finish when he/she no longer needs pain medicine or at 3 months, whichever comes first.

**5. INFORMATION ABOUT RISKS AND BENEFITS**

**5.1 What risks will my child face by taking part in the study? What will the researchers do to protect my child against these risks?**
Side effects can occur with any medicine, and the risks for Painaway are similar to alternative forms of narcotic therapy for moderate to severe pain. Based on past experiences, the primary (most common) side effects of Painaway occur in about 30 out of 100 patients (30%) and include light-headedness or dizziness, nausea and vomiting, or constipation. Rarely, in less than 3 out of 100 patients (3%), excessive sleepiness and/or slowed

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breathing that require a decrease in the dose of Painaway or a medicine to reverse its effects may occur. Side effects will be treated with routine measures, at the discretion of your child’s care providers.

Painaway-CR (controlled release Painaway) tablets are to be swallowed whole, and are not to be broken, chewed, or crushed. The controlled release tablet is designed to release pain medication over an extended period of time. Taking broken, chewed or crushed Painaway tablets could lead to the rapid release and absorption of a potentially harmful dose of Painaway requiring emergency treatment. Your child should not participate if he/she cannot swallow pills or tablets.

There is a possibility of drug interaction with Painaway and other drugs such as sedatives, sleeping pills, and antidepressants that could result in increased effects of either or both drugs. In addition, there are some other medications that might increase or decrease their effects. Therefore, you must tell your doctor of all drugs your child is currently taking, and he will advise you of what he/she can or cannot take during the study. As with any drug, your child may experience an allergic reaction that could be life threatening.

The potential side effects of blood collection are low and include pain and/or bruising at the puncture site. To minimize these effects, samples will be taken from an IV catheter whenever possible, and standard blood-collecting techniques will be used.

**Inconveniences:**
The assessments that are done during this study may be bothersome for some children. These assessments will be done, as much as possible, when he/she is awake, or during other routine nursing activities.

**Risk Associated With Pregnancy:**
Because participation in this study may involve risks to unborn children, if your child is a female of childbearing potential, she may participate in this study only if there is a negative pregnancy test and she agrees not to attempt to become pregnant during the study. If your child is having surgery, a pre-operative pregnancy test will suffice. Acceptable forms of birth control include but are not limited to the following: abstinence, birth control pills, intrauterine device, Depo-Provera and implant preparations.

**Unforeseen Risks:**
Problems and side effects, which are unknown at this time, may occur. If new information becomes known during your participation, you will be told so that you can reconsider staying in the study. Such information will also be provided to the Institutional Review Board (IRB), and a new informed consent may be required.

5.2 What happens if my child gets hurt, becomes sick, or has other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, there may still be problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that your child experiences during this study. You should also tell your child’s regular doctors.

5.3 If my child takes part in this study, can he/she also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to your child. It may also affect the results of the studies. You should not have your child take part in more than one study without approval from the researchers involved in each study.

5.4 How could my child benefit if I let him/her take part in this study? How could others benefit?
Your child will receive an analgesic that may relieve pain and will have access to additional pain medications, as appropriate. The treatment your child is given may or may not directly benefit him or her, however, approximately 75 out of 100 patients (75%) who have received Painaway in the past have had good pain relief. Your child’s part will help us learn about how to best manage pain in children who may need Painaway for medium to severe pain.

There is no guarantee that the doctor will continue to prescribe the study medication at the end of the study.
5.5 Will the researchers tell me if they learn of new information that could change my willingness to let my child stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to have your child stay in this study. If new information is provided to you after you have joined the study it is possible that you may be asked to sign a new consent form that includes the new information.

6. OTHER OPTIONS

6.1 If I decide not to let my child take part in this study, what other options do I have?
If you or your child do not wish to participate in this research study, he or she will receive treatment according to the routine practice and his or her care will in no way be jeopardized. Standard practice in this hospital may include administering the same analgesics (Painaway-IR or Painaway-CR), and some of the same assessments (ex. Pain assessment) as described above, however, none of the additional blood tests will be done for children who do not participate in the study.

7. ENDING THE STUDY

7.1 If I want my child to stop participating in the study, what should I do?
You and your child are free to leave the study at any time. If your child leaves the study before it is finished, there will be no penalty to him/her. Your child will not lose any benefits to which he/she may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information” (below).

7.2 Could there be any harm to my child if we decide to leave the study before it is finished?
If your child drops out of the study, it is important to follow your doctor’s directions about treating pain. Abruptly stopping pain medicines can cause symptoms of withdrawal. Therefore, medicines like those used in this study need to be weaned off slowly.

7.3 Could the researchers take my child out of the study even if we want to continue to participate?
Yes. There are many reasons why the researchers may need to end your child’s participation in the study. Some examples are: The researcher believes that it is not in your best interest to stay in the study, your child becomes ineligible to participate, your child’s condition changes and he/she needs treatment that is not allowed while he/she is taking part in the study, you do not follow instructions from the researchers and, the study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my child’s health plan be billed for any costs of the study?
SciFi Pharma will cover all expenses related to your child’s participation in this study. There are no additional costs to you or your insurance carrier if you participate in this study. The pain medications, Painaway-IR and Painaway-CR will be given to you free of charge for the entire time your child is in the study. After participation in the study stops, you will be responsible for payment of any pain medicines.
By signing this form, you do not give up your right to seek payment if your child is harmed as a result of being in this study.

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8.2 Will I or my child be paid or given anything for taking part in this study?
You will receive a $5.00 gift certificate at the end of your participation.

8.3 Who could profit or financially benefit from the study results?
SCiFi Pharma

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR CHILDS PROTECTED HEALTH INFORMATION

The information below describes how your child’s privacy and the confidentiality of his/her research records will be protected in this study.

9.1 How will the researchers protect my child’s privacy?
Your child’s information will be kept in our research records, in the locked offices of the researchers. Only those people involved in the study will have access to these records. Your child’s name and registration number will not be recorded onto any of the research records, but will be kept separately from those records so that we can review medical information, if necessary.

9.2 What information about my child could be seen by the researchers or by other people? Why? Who might see it?
Signing this form gives the researchers your permission to obtain, use, and share information about your child for this study, and is required in order to take part in the study. Information about your child may be obtained from any hospital, doctor, and other health care provider involved in your child’s care, including: Hospital/doctor’s office records, including test results (X-rays, blood tests, urine tests, etc.), all records relating to your child’s condition, the treatment received, and his/her response to the treatment, and billing information.

There are many reasons why information about your child may be used or seen by the researchers or others during or after this study. Examples include: 1) The researchers may need the information to make sure your child can take part in the study; 2) the researchers may need the information to check your child’s test results or look for side effects; 3) University, Food and Drug Administration (FDA), and/or other government officials may need the information to make sure that the study is done in a safe and proper manner; 4) Study sponsors or funders, or safety monitors or committees, may need the information to: make sure the study is done safely and properly, learn more about side effects and analyze the results of the study. 5) The researchers may also need to use the information to create a databank of information about your child’s condition or its treatment; 6) Information about your child’s study participation may be included in his/her regular UMHS medical record; 7) If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes; and 8) Federal or State law may require the study team to give information to government agencies, for example, to prevent harm to your child or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who your child is.

9.3 What happens to information about my child after the study is over or if I cancel my permission?
As a rule, the researchers will not continue to use or disclose information about your child, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about your child to continue to be used or disclosed, even after you have canceled your permission or the study is over. Examples of reasons for this include: 1) To avoid losing study results that have already included your child’s information, 2) To provide limited information for research, education, or other activities. (This information would not include name, social
security number, or anything else that could let others know who your child is), and 3) To help University and government officials make sure that the study was conducted properly.

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System’s privacy policies. For more information about these policies, ask for a copy of the University of Michigan Notice of Privacy Practices. This information is also available on the web at http://www.med.umich.edu/hipaa/npp.htm. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission expire?
Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?
Please contact the researchers listed below to: 1) Obtain more information about the study, 2) Ask a question about the study procedures or treatments, 3) Talk about study-related costs to you or your health plan, 4) Report an illness, injury, or other problem (you may also need to tell your regular doctors), 5) Leave the study before it is finished and, 6) Express a concern about the study.

Principal Investigator: Dr. J Doe
Study Coordinator:
Mailing Address:
Telephone:

You may also express a concern about a study by contacting the Institutional Review Board listed below, or by calling the University of Michigan Compliance Help Line.

University of Michigan Medical School Institutional Review Board (IRBMED)
Telephone: 734-763-xxxx

If you are concerned about a possible violation of your privacy, contact the University of Michigan Health System Privacy Officer at 1-888-296-xxxx.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?
Your signature in the next section means that you have received copies of all of the following documents:

This "Consent to be Part of a Research Study" document. (Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)
12. SIGNATURES

**YOUR SIGNATURE BELOW MEANS:**
I understand the information printed on this form.
I have discussed the study, its risks, benefits, and other choices with ________________.

My questions so far have been answered.

I understand that I will receive a copy of this form at the time I sign it and that one will be kept in the research files and possibly my child’s medical record.

Name of child (Print legal name):__________________________________________

Patient ID:__________________________ Date of Birth:__________________________

**Parent or guardian:**

Name (Print legal name): ________________________________

Signature ________________________________ Date: __________________

Check Relationship to Subject:

☐Parent  ☐Legal Guardian  ☐Other:

**Principal Investigator (or Designee):**

I have given this research subject (or his/her legally authorized representative, if applicable) information about this study that I believe is accurate and complete. The subject has indicated that he or she understands the nature of the study and the risks and benefits of participating.

Name:______________________________________________ Title:______________________________

Signature:___________________________________________ Date of Signature:__________________________

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