IRB Approved: 8/29/2017
Approval Expires: 8/23/2018

OREGON HEALTH & SCIENCE UNIVERSITY

MED. REC. NO. _____
NAME _____
BIRTHDATE _____

IRB#: 9681

Clinical Research Consent Summary

You are being asked to join a research study. You do not have to join the study. Even if you decide to join now, you can change your mind later.

If you decide to join, you will be asked to sign a consent form, which shows you give permission to be in the study, and an authorization form, which shows you give permission for us to use and disclose (release) your health information for the study.

1. The purpose of this study is to learn more about pain control after surgery performed for scoliosis.
2. In this study, we will learn about a drug called gabapentin. **Gabapentin will be called "the study drug" throughout this form.** We want to learn
    a. If using the study drug decreases the amount of pain felt by the subject after scoliosis surgery;
    b. If using the study drug decreases the amount of narcotic medication needed to control pain after scoliosis surgery;
    c. If using the study drug improves the satisfaction of the family regarding pain control;
    d. If the study drug is safe; and
    e. What side effects, if any, are caused by the study drug.
3. We do not know if the study drug works.
4. The study drug has not been approved by the Food and Drug Administration (FDA) for this particular indication.
5. The study drug is a tablet taken just prior to surgery and then every eight hours for the four days after surgery.
6. You will have a 50/50 chance of receiving the study drug vs. a placebo. A placebo is a pill that looks like the study drug but has no real medicine in it. You will not know which one you get.
7. If you join the study you will receive the study drug for 4 days, including just prior to your surgery. We will continue to track opioid usage, pain scale ratings, and sedation ratings during your entire time in the hospital. You will be asked to complete a survey at the time of discharge to evaluate your satisfaction with control of pain after surgery.
8. There are risks involved in participating in the study, some of which may be very serious. These risks include allergic reaction, emotional instability, hostility, confusion, and restlessness. Gabapentin may also cause temporary dizziness, sleepiness, and other symptoms and signs of decreased consciousness. Other potential risks are listed below.

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Clinical Research Consent and Authorization Form

TITLE: Pain Control in Pediatric Posterior Spine Fusion Patients: The Effect of Gabapentin on Post-operative Opioid Use and Patient Satisfaction

PRINCIPAL INVESTIGATOR:

CO-INVESTIGATORS:

PURPOSE:

"You" means you or your child in this consent form.

You have been invited to be in this research study because you are going to have surgery for scoliosis. The purpose of this study is to learn if gabapentin reduces the pain of surgery and decreases the amount of narcotic medication needed after surgery to control post-operative pain.

Gabapentin will be called "the study drug" throughout this form.

By decreasing the amount of narcotic medication needed to control pain after spine surgery the study drug may decrease the narcotic-associated side effects after spine surgery such as nausea, vomiting, inability to urinate and constipation. It may also decrease the overall amount of pain experienced after surgery for scoliosis.

Right now, the study drug is not approved for use for post-operative pain management after spine surgery in the United States because we do not know enough about it.

This study will require no extra visits to the clinic and will be completed during your admission for scoliosis surgery.

Fifty-five subjects will be enrolled in this study at OHSU.

PROCEDURES:

You will be asked about participating in the study either at the time you are indicated for scoliosis surgery in the office or on the day of surgery. This discussion can take up to one-half hour.

This is a randomized study. Neither you nor the investigator can choose whether you get gabapentin or the placebo. A placebo is a pill that looks like the study drug but has no real medicine in it. Half of the subjects in this study will get the placebo.

You and the investigators will not know which pill you are taking. The study is done this way because knowing whether you are getting the study drug can change the results of the study. If

you start having serious side effects from the study drug, the investigators can find out what you are taking in order to help you. Please ask the investigator if you have any questions at all about this kind of study.

Once you have agreed to participate in the study you will be assigned to one of two groups, the study drug group or the placebo group.

Just prior to surgery you will receive the study drug or the placebo. You will continue to receive it every 8 hours for four days following surgery. This will take no extra time for you.

During your admission you will be evaluated for your level of perceived pain, your sedation level, occurrence of narcotic and non-narcotic side effects such as nausea, vomiting, allergic reaction, and overall narcotic drug usage. These steps will take no extra time for you.

At the time of discharge you will be asked to fill out a brief pain perception assessment survey. This asks questions about how severe the pain may have been during the admission and whether the staff were responsive to your needs with respect to pain management. This should take less than one-half hour.

RISKS AND DISCOMFORTS:

You have been invited to be in this research study because you are scheduled to have a posterior spine fusion with instrumentation for severe scoliosis. That procedure is not experimental and is not part of this study, and the risks will be discussed with you separately.

There are risks involved in participating in the study, some of which may be very serious.

Study Drug Risks
Risks include allergic reaction, which may appear as a rash, hives, fever, swollen lymph nodes, swollen lips/tongue, unusual bruising, and/or severe fatigue.

Other potential risks include:

- changes in blood pressure,
- swelling in the extremities
- joint pains.

There are risks of behavioral changes, emotional instability, hostility, confusion, and restlessness.

The study drug may also cause

- blurred or abnormal vision,
- temporary dizziness,
- sleepiness and other symptoms and signs of decreased consciousness when given with narcotic medications such as morphine. For these reasons it is advised not to operate complex machinery while taking gabapentin.

The effects of gabapentin on pregnant patients, fetuses and in nursing mothers/infants have not been well studied and are potentially risky to pregnancy.

Discomforts such as fatigue, diarrhea, dry mouth, constipation, nausea and vomiting have been reported.

You may have some side effects we do not expect because we are still learning about gabapentin.

One risk to taking part in this study is that the study drug or the dose you receive may not be effective in helping to decrease your pain after scoliosis surgery. This means you may spend time in the study and experience side effects of taking a drug that may not provide you with any health-related benefits.

There are several drugs (prescription and non-prescription) that may cause problems when taken with the study drug. The investigator will carefully review all of the drugs you are taking before giving you the study drug. If any other health care provider prescribes any new drug(s) for you while you are in this study, please tell the investigator before you take the new drug. You could also have that provider talk to the investigator before prescribing the new drug. Do not take any new over-the-counter drugs while you are in this study unless you first check with the investigator. The subject will be monitored for these side effects, and you are encouraged to report any behaviors or symptoms of concerned to healthcare providers.

BENEFITS:
You may or may not personally benefit from being in this study. However, by serving as a subject, you may help us learn how to benefit patients in the future.

ALTERNATIVES:
You may choose not to be in this study. If you choose not to be in this study you will not receive gabapentin during your admission for scoliosis surgery but you will continue to receive all of the other medications that we use to control pain in this situation including narcotic medications, anti-spasmodics (such as Valium), acetaminophen and ketorolac.

CONFIDENTIALITY
We will take steps to keep your personal information confidential, but we cannot guarantee total privacy.

We will create and collect health information about you as described in the Purpose and Procedures sections of this form. Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving permission (also called authorization) for us to use and disclose your health information as described in this form.

The investigators, study staff, and others at OHSU may use the information we collect and create about you in order to conduct and oversee this research study.

We may release this information to others outside of OHSU who are involved in conducting or overseeing research, including:

- The Food and Drug Administration
- The Office for Human Research Protections, a federal agency that oversees research involving humans

We will not release information about you to others not listed above, unless required or permitted by law. We will not use your name or your identity for publication or publicity purposes, unless we have your special permission.

When we send information outside of OHSU, it may no longer be protected under federal or Oregon law. In this case, your information could be used and re-released without your permission.

We may continue to use and disclose your information as described above indefinitely.

Some of the information collected and created in this study may be placed in your OHSU medical record. While the research is in progress, you may or may not have access to this information. After the study is complete, you will be able to access any study information that was added to your OHSU medical record. If you have questions about what study information you will be able to access, and when, ask the investigator.

COMMERCIAL DEVELOPMENT:
Information about you or obtained from you in this research may be used for commercial purposes, such as making a discovery that could be patented or licensed to a company. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your information.

COSTS:
Some of the services or items in this study are part of the regular treatment for your condition. These would be performed or used even if you were not in this study. The costs for these services or items will be billed to your insurance. You will be responsible for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may be responsible for, contact your insurance company. If you are uninsured, you will be responsible for these costs.

You will not be billed for the costs of any services or procedures that are required by the study but are not considered part of your regular treatment.

LIABILITY:

If you believe you have been injured or harmed while participating in this research and require immediate treatment

You have not waived your legal rights by signing this form. If you are harmed by the study drug or study procedures, you will be treated. Oregon Health & Science University does not offer to pay for the cost of the treatment. Any claim you make against Oregon Health & Science University may be limited by the Oregon Tort Claims Act (ORS 30.260 through 30.300). If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

PARTICIPATION:
If you have any questions regarding your rights as a research subject, you may contact the OHSU Research Integrity Office at (503) 494-7887.

You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study.

If you do join the study and later change your mind, you have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. If you choose not to join any or all parts of this study, or if you withdraw early from any or all parts of the study, there will be no penalty or loss of benefits to which you are otherwise entitled,

including being able to receive health care services or insurance coverage for services. Talk to the investigator if you want to withdraw from the study.

If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization. If you choose to withdraw there will be no ramifications with respect to your continued hospitalization or post-operative care.

You may be removed from the study if you develop serious side effects or if you do not follow study instructions.

If in the future you decide you no longer want to participate in this research, we will destroy all your information. However, if your information is already being used in an ongoing research project and if its withdrawal jeopardizes the success of the entire project, we may ask to continue to use it until the project is completed.
We will give you any new information during the course of this research study that might change the way you feel about being in the study.

Your health care provider may be one of the investigators of this research study and, as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way involved in this project. You do not have to be in any research study offered by your physician.

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.

SIGNATURES:

Your signature below indicates that you have read this entire form and that you agree to be in this study.

We will give you a copy of this signed form.

Subject/Parent/Guardian/Legally Authorized Representative Printed Name	Subject/Parent/Guardian/Legally Authorized Representative Signature	Date
Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

Complete if the participant is not fluent in English and an interpreter was used to obtain consent. Participants who do not read or understand English must not sign this full consent form, but instead sign the short form translated into their native language. This form should be signed by the investigator and interpreter only.

Print name of interpreter: _____

Signature of interpreter: _____ Date: _____

An oral translation of this document was administered to the subject in _____ (state language) by an individual proficient in English and _____ (state language).

See the attached short form for documentation.