

**ASSENT INFORMATION AND CONSENT FORM AND AUTHORIZATION TO
USE AND DISCLOSE MEDICAL INFORMATION**

PROTOCOL XXXXXXXXXXXXXXXXXXXX

TITLE:

SPONSOR:

INSTITUTION: St. John's Medical Research
St. John's Health System, Inc.

INVESTIGATOR:

STUDY PHASE: III

PATIENT NAME: _____
Last First M.I.

**PLEASE INITIAL THE BOTTOM OF EACH PAGE WHEN YOU HAVE HAD
ALL OF YOUR QUESTIONS ANSWERED TO YOUR SATISFACTION.**

INTRODUCTION

This form may use words you do not understand. Please ask the study doctor, or his or her assistant to explain anything you do not understand. If you do not want to be in this study, you do not have to. No one will be upset if you do not want to be in the study or if you change your mind later and want to stop.

This research is funded by (study sponsor). St. John's Medical Research uses these funds to cover all study-related expenses including laboratory tests, physician fees, patient payments, and other administrative costs.

WHAT IS THIS STUDY ABOUT?

The study doctor wants to find out if a medicine called XXXXXXX is safe and if it can help people with partial seizures who are already taking seizure medicines. This is called a "research study."

You may be able to be in this study because you have partial seizures, and you are currently taking some medicines that don't control your seizures enough. The doctor wants to know if you want to keep taking your regular medicines and also take XXXXX in this research study.

DO I HAVE TO BE IN THIS STUDY?

You do not have to be in the study if you don't want to.

Even if you say you want to be in the study now, you can stop later if you change your mind. If you change your mind later, tell the doctor.

You can ask the doctor or nurse questions before you make up your mind. You can also talk to your mom or dad and ask to read the information the doctor gives them.

WHAT WILL HAPPEN TO ME IN THIS STUDY?

If you want to be in the study, you will take some pills 2 times a day for about 14 weeks. You will take up to 8 of these pills each day. In addition, you will keep taking your regular medicines for your seizures.

The pills that the doctor gives you may be XXXXXXXX, or they may be pills called placebo. Placebo pills are pills that look like XXXXXX but don't have any medicine in them. You, your mom and dad, and the doctor will not know if you are taking XXXXXXXX or placebo pills.

You will come to the doctor's office about 6 more times in the next 26 weeks.

Here are some things the doctor or nurse will do:

- Ask you about your seizures and about how you are feeling.
- Ask you about all of the medicines you are taking.
- Ask you to use a diary to keep track of all of your seizures. If you want, your mom or dad can help you with this.
- Give you a check-up. You should ask the doctor what he or she will do during the exam.
- See how tall you are and see how much you weigh.
- Take your blood pressure by putting a band around your arm. This will squeeze your arm for about a minute.
- Listen to your heart beat, listen to you breathe in and out, and take your temperature.
- Do a test to check the electrical activity in your heart. The doctor or nurse can tell you about this test.
- Take your blood with a needle.
- Ask you to urinate (pee) in a cup.
- Test some of your urine (pee) for drugs and alcohol. The doctor or nurse will tell you if the test results show you have used any drugs or alcohol. Depending on the laws of your state, the doctor or nurse may also tell your mom or dad about the results of the drug and alcohol tests. If you are using drugs or alcohol, you cannot be in the study.

- If you are a girl and have had your period, the doctor or nurse will test your blood and urine (pee) to see if you are pregnant. The doctor or nurse will tell you if the test results show you are pregnant. Depending on the laws of your state, the doctor or nurse may also tell your mom or dad about the results of the pregnancy test. If you are pregnant, you cannot be in the study.
- If you are a girl and have had your period, the doctor may talk to you about birth control options and might require you to use one of those options in order to stay in the study.

The doctor or nurse will also call you or your mom or dad in between your doctor's visits to ask about how you are feeling and to make sure you (or your mom or dad) are using the diary to keep track of your seizures.

If you do not want to do any of these things, you can say you do not want to be in the study.

CAN ANYTHING BAD HAPPEN TO ME IN THIS STUDY?

People who have a lot of seizures should not drive a car, or be in high places or around moving machinery because it could be dangerous to themselves or to others. Ask the doctor if you have questions about this.

The pills might not help you. Here are some things that might happen:

- headache
- feeling dizzy
- feeling tired
- feeling sleepy
- feeling like you may throw up
- seeing double
- not having as much of an appetite
- feeling like you have a cold
- blurry vision
- runny nose
- feeling uncoordinated (like you can't control your movements very well)
- eyes moving without you wanting them to
- moving a lot
- convulsion (your muscles moving when you don't want them to)
- ear infection
- nosebleed
- seizures that last a long time
- more seizures
- stomach ache
- feeling nervous
- constipation (having a hard time going to the bathroom)

- back pain
- bruising
- acne (pimples)
- flu
- feeling pain when you have your period

You might also feel other things. While you are in the study, you have to tell the doctor or your mom or dad if you feel sick or if you take any medicines. You or your mom or dad can call the doctor at (417) 820-9123.

The doctor or nurse will take your blood with a needle. Some problems you might have from this are:

- It may hurt.
- You may get a bruise.
- You may feel dizzy or faint.
- You may get a blood clot.
- You may get an infection.

ARE THERE RISKS TO ME IF I AM PREGNANT DURING THE STUDY?

Girls cannot be in this study if they are:

- pregnant
- planning to become pregnant during the study
- nursing a child

If a girl is pregnant or nursing a child while taking E2080, there may be risks to the unborn baby or nursing child. Nobody knows what these risks are right now. Some drugs cause girls to have their babies prematurely (early) or to have babies with birth defects.

The doctor may require girls who join the study to have pregnancy tests during the study. A pregnancy test does not keep you from becoming pregnant. If you are a girl who has had her period, the doctor will talk to you about birth control options you must use during the study. Some types of birth control will not work when you are taking certain drugs.

If you think you are pregnant during the study, you must tell the doctor immediately. If you become pregnant, you will have to leave the study. The doctor may ask for information about the pregnancy and the birth of the baby. The doctor may share this information with the sponsor and the St. John's Institutional Review Board (IRB).

WILL BEING IN THIS STUDY HELP ME?

Your seizures might get better if you are in this study, but the doctor can't be sure that being in this study will help you. Your seizures might even get worse. If you are in this study, you might help doctors find out things that will help other children some day.

WHO CAN I TALK TO ABOUT THE STUDY?

You can ask questions about the study any time. You can call the doctor any time.

If you want to ask questions about what it means to be in a research study, you or your mom or dad can call the St. John's IRB at 417-820-5397.

DO YOU WANT TO BE IN THIS STUDY?

Please sign below if you want to be in this study, but remember: You don't have to be in this study if you don't want to.

Signature of Patient or Legal Representative Date* / ____ / ____ Time : ____ AM/PM

Printed Name of Patient

Printed Name of Legal Representative Relationship to Patient

Signature of Person Administering Consent Date* / ____ / ____ Time : ____ AM/PM

Printed Name of Person Administering Consent

Signature of Investigator Date* / ____ / ____ Time : ____ AM/PM

Printed Name of Investigator

- Date must be personally entered by individual signing the consent form.