**ASSENT FORM**

**TITLE OF STUDY: ESETT:** Established Status Epilepticus Treatment Trial

**PRINCIPAL INVESTIGATOR:** <<Name>>

**PHONE NUMBER:** (xxx) xxx-xxxx

**What is research?**

Research is a way to test new ideas. Research helps us learn new things. Research is sometimes called “study” or “research study” but they all mean the same thing.

We are asking you to continue your participation in a research study that you were enrolled in while you were having a seizure.

Being in research is your choice. You can say Yes or No. Whatever you decide is OK. We will still take good care of you whether you say yes or no.

**Why are we doing this research?**

ESETT is an emergency medicine study designed to try to save and improve the lives of children and adults who experience a seizure lasting longer than five minutes without stopping on its own or without waking up. A person whose seizure does not stop even after receiving a full dose of medicine (like valium) to make it stop is considered to have Established Status Epilepticus or ESE.

This study plans to find out the safest and fastest treatment for ESE. Following the study medicine, additional medication per patient response and local protocol could be given along with monitoring in the Emergency Department (ED).

**What will happen in this research?**

You have received a copy of this form because you had a seizure that would not stop even after you were given a full dose of medicine to make it stop. This medical condition is known as established status epilepticus (ESE). You were automatically put into the ESETT study under a special research rule that allows research doctors to enroll you without asking you first. This is because of your condition, and because you needed to be treated quickly.

This study plans to look at three commonly used medicines given in the emergency departments for seizures lasting longer than 5 minutes: phenoytoin (fPHT), valproic acid (VPA), and levetiracetam (LVT), to learn which one is safer and faster at stopping seizures. The best possible outcomes in patients who experience a long lasting seizure that will not stop even after receiving a full dose of medicine to make them stop are likely to depend on a treatment that leads to a quick stop of their seizure.

Your part in the study is mostly over. You won’t be given any more study medicine, have any tests done or be asked to do anything as part of this study. Now, we just want to find out about your stay in the hospital. We want to write down any problems you had, how long you were here, and things like that.

Your parents have to agree to let you volunteer to do this study.

If you do not want to continue in this study you do not have to. You can say no anytime you want.

**What are the bad things that can happen from this research?**

There are some risks or things that can go wrong because of the medicine you were given in this study, however, all three study medicines are commonly used to treat long-lasting seizures. The risks of the study medicines are similar to those that you might have experienced if you received treatment for your seizure, had you not been enrolled in the study. You won’t get any more medicine, so these things can’t happen anymore because of the study.

You may have some redness, bruising, and soreness in the area where the IV was placed in your arm.

Risks and possible side effects of any of the study medicines include drowsiness, dizziness, an allergic reaction, or pain, discomfort, or inflammation where you got the injection in the vein.

Additionally:

Fosphenytoin may cause

* Low blood pressure
* Slow heart rate
* Swelling of the blood vessels
* Skin rash

Levetiracetam may cause

* Nervousness, confusion or aggression

Valproic acid

* Skin rash
* Liver or pancreas problems

There may be other unknown risks as well. Neither you nor the study team will know which study medicine you were given until the study is over.

There is also a risk that some of your personal information may be seen by people other than your doctors and nurses. We will do our best to keep all of your medical information that we collect private.

You may experience some, all, or none of the risks related to the study medicine that you received. There may be other risks that we don’t know about.

**What are the good things that can happen from this research?**

Because we do not know which medicine is better for seizures, you may have gotten a better medicine to treat your seizure.

If you decide to continue to be a part of this study you will be watched extra carefully for side effects of the seizure and the medicine you were given to stop the seizure.

You will also be helping other children who have seizures in the future.

**What else should you know about the research?**

Being in the research is your choice. If you say yes now and change your mind later that is also Okay. You can stop being in the research at any time.

If you want to stop being in the research, all you have to do is tell one of the doctors or nurses here at the hospital.

Take all the time you need to make your choice. Ask us any questions you have. It is okay to ask more questions after you decide to be in the research. You can ask questions at any time.

**What other options do I have?**

If you do not want to stay in this study you will still receive the best care that we provide normally for seizures.

You will be given a copy of this form to take home with you.

**CHILD’s ASSENT:**

After you have read this form and talked about this research with your parent(s) and the doctors or nurses you need to decide if you want to stay in this research. If you want to stay in this research you should sign or write your name below.

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Child’s Assent Date Time

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The following should be completed by the study member conducting the assent process if the child agrees to be in the study. Check all that apply.

* The child is capable of reading and understanding the assent form and has signed above as documentation of assent to take part in this study.
* The child is not capable of reading the assent form, but the information was verbally explained to him/her. The child signed above as documentation of assent to take part in this study.
* The child had ample opportunity to have his or her questions answered.

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Signature of Person Obtaining Assent Date Time