ADOLESCENT ASSENT FORM FOR YOUTH AGES 12-17

*Version November 2014*

Your parent has given permission for you to be in a project called a research study. But first, we want to tell you all about it so you can decide if you want to be in it. If you don’t understand, please ask questions.

1. **What is the name of the study?**

Established Status Epilepticus Treatment Trial (ESETT): A multicenter, randomized, blinded, comparative effectiveness study of fosphenytoin, valproic acid, or levetiracetam in the emergency department treatment of patients with benzodiazepine-refractory status epilepticus.

1. **Who is in charge of the study?**

The doctor in charge of the study is Dr. Jonathan Bennett

1. **What is the study about?**

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).

1. **Why are you asking me about this study?**

You have already received treatment in this study because you came in to the Emergency Room having non-stop seizures. 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 are asking for your permission to follow your stay while you are in the hospital until you are discharged or thirty days, whichever is shorter. We want to write down any problems you have, how long you were here, and things like that.

1. **What will happen to me in the study?**

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: fosphenytoin (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 parents will be asked to allow you to continue in this study.

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

1. **Will I be paid to be in this study?**

You will not be paid for being in this study.

1. **Do I have to be in the study?**

You don’t have to continue being in the study if you don’t want to. You can stop being in it at any time. Nobody will be upset with you if you don’t want to be in the study or if you want to stop being in the study. The doctors and nurses will take care of you as they have in the past. If you have any questions or don’t like what is happening, please tell the doctor or nurse.

You have had the study explained to you. You have been given a chance to ask questions. By writing your name below, you are saying that you want to be in the study.

|  |  |  |
| --- | --- | --- |
| Name of Adolescent (**Print**) |  | Date |

|  |
| --- |
| Signature of Adolescent |

|  |  |  |
| --- | --- | --- |
| Name of Person Obtaining Assent (**Print**) |  | Date |

|  |
| --- |
| Signature of Person Obtaining Assent |