ASSENT FORM FOR CHILDREN AGES 7 – 11

*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?**

This study is designed to try to save and improve the lives of children who experience a seizure lasting longer than five minutes without stopping on its own.

This study plans to find out the safest and fastest treatment for treating these non-stop seizures.

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

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.

You received one of three common drugs used to treat your non-stop seizures in the Emergency Room.

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 follow you throughout your stay in the hospital until you go home.

Your parents will be asked to allow you to continue 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. If you are in the study, you can stop being in it at any time. Nobody will be upset with you. No matter what you decide, the doctors and their helpers will take care of you just like they did before. If you have any questions or don’t like what is happening, please tell your parent, the doctor or helper.

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.

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

|  |
| --- |
| Signature of Child |

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

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

[ ]  The assent information was read to the child by the person obtaining assent.

[ ]  The child read the assent him / herself.