**1. Cover slide**

*Welcome to the study overview of the ESETT study. The following slides will give you some background introduction about a study we are planning to conduct in the Emergency Department at Primary Children’s Hospital. After you view the slides, we will ask you to participate in a survey so you can tell us how you feel about the information that is presented.*

**2. Emergency Department Research**

*A research study is a way for doctors to find new information about a disease, or the best way to treat a condition.*

*Research helps doctors develop the best treatment for patients in all areas of medicine, including emergency medicine.*

*Conducting research in an emergency department can be difficult because the patients can be very sick.*

**3. What is a seizure?**

*Seizures are an example of a common condition that may be studied in the Emergency Department. A seizure usually causes jerking activity of the body and can cause unconsciousness.*

*Epilepsy is the most common cause of seizures.*

*Other causes include:*

*Brain injury or tumor in the brain*

*A Stroke*

*Alcohol or drug use*

*High fever can also cause a seizure, especially in children*

**4. What is Status Epilepticus?**

*Status Epilepticus occurs when a person experiences a seizure that does not stop. It is a medical emergency! Patients with status epilepticus are given a medicine called a benzodiazepine, like valium, to make their seizures stop.*

**5. What are the dangers of status epilepticus?**

*Status epilepticus is serious and can be life threatening. It can cause:*

* *Brain damage*
* *Low oxygen*
* *Direct nerve damage*
* *Other tissue damage to muscles and kidney*
* *And even cause death.*

*The longer a seizure continues the greater the chance the patient could die from their seizure.*

**6. What is ESE?**

*If a seizure continues after treatment with a benzodiazepine like valium, this is known as Established Status Epilepticus, or ESE. ESE may be treated with many different medicines. Sometimes two or more drugs may be needed to stop the seizure. Doctors do not know which drug is best for stopping Established Status Epilepticus. More research is needed in order to gain information about which medicine is best.*

**7. The ESETT Study**

*Doctors at Primary Children’s Hospital are joining 39 other hospitals across the country to conduct a study to find out the best way to treat Established Status Epilepticus (ESE). The study is called ESETT, which stands for Established Status Epilepticus Treatment Trial.*

**8. ESETT**

*ESETT is a research study designed to find out which of three commonly used drugs is best to stop established status epilepticus.*

*The medicines being studied are:*

*Fosphenytoin, also called Cerebyx*

*Valproic acid, sometimes called Depakote, and*

*Levetiracetam, also known as Keppra*

**9. Who will be included?**

*At our hospital, any patient two years of age and older may be included in the study if they are being treated for ongoing or recurring seizure activity lasting longer than 5 minutes AND has already been given an adequate dose of benzodiazepine, like Valium, in the past 5-30 minutes. This patient is in Established Status Epilepticus and needs to be given a medicine, like the ones we are studying, to try to stop the seizure.*

**10. Who cannot be included?**

*Patients will NOT be enrolled in they are:*

* *Under 2 years of age,*
* *Have low or high blood sugar,*
* *Are known to be pregnant or*
* *A prisoner or known to be in police custody.*

*Patients with a medical alert tag that includes the phrase “ESETT declined” will also not be enrolled.*

**11. How will the study work?**

*Enrollment in the study may happen anytime a patient comes to our Emergency Department with established status epilepticus.*

* *Every patient coming to the ED who is eligible will be considered for the study.*
* *Everyone in this study will be treated with a medication for his or her seizure.*
* *Patients who are enrolled in the study will receive a single dose of one of the three drugs being studied through an intravenous line or IV.*

**12. How will the study drug be chosen?**

*In the beginning everyone will have the same equal chance of receiving any of the three study medicine, like flipping a coin.*

*As the study goes along if one study drug seems to be helping to stop a seizure faster, the chances of receiving that study drug will go up.*

*Once there is enough proof that one drug is indeed working better or worse, the study will be stopped.*

**13. What else will happen?**

*While in the study, participants may have a teaspoon of blood taken to test for the study medicine in the blood.*

*If the seizure does not stop doctors will follow their normal procedures to try to make it stop.*

*More medicine may be given – this may be one of the study medicines or a different medicine.*

*The study team will monitor the patient while he or she is in the hospital.*

**14. What are the risks?**

*There are risks involved in participating in research. Risks and possible side effects of any of the medicines used in this study may include:*

* *drowsiness,*
* *dizziness, or*
* *an allergic reaction*

*Additionally:*

* *Fosphenytoin may cause low blood pressure, slow heart rate, inflammation of the blood vessels, or skin rash.*
* *Levetiracetam may cause behavior changes such as nervousness, confusion, or aggression.*
* *Valproic acid may also cause a skin rash and liver or pancreas problems.*

*There may also be other risks that we are unaware of at this time.*

**15. All three drugs are commonly used to treat seizures**

*It’s important to know that doctors commonly use all three of the study drugs to treat seizures. The risks of the study medicines are the same whether they are given in the study or for treatment of seizures outside of this study.*

**16. What are the Benefits?**

*There are some benefits of participating in the ESETT study.*

* *Because we do not know which of the study drugs is better, study participants may benefit from receiving a better medicine.*
* *The information may help us to provide more effective drugs in the future for patients with seizures.*

**17. How is this study different?**

*This study is different from most other studies, especially those studies that are conducted outside of the emergency department.* ***Click forward to the next slide to learn more about these differences.***

**17a.** *In most studies, a study representative explains the study and it’s risks and benefits to a participant before any study procedures have taken place. The person is able to ask questions about the study, and decide to be in the study or not. This process is called “Informed Consent”.*

**17b.** *In this study, patients with seizures are unconscious and can’t give permission to participate in the study.*

*The study medicine has to be given quickly to stop the seizure activity. So, there is not time to explain the study and ask for consent from the family who may be with the patient at the time of the emergency.*

**18. Rules for Emergency Research**

*With Emergency Research like ESETT, it's not possible to get informed consent before treating the patient. The federal government and local research committees, called IRBs, allow for this kind of research following procedures called “Exception From Informed Consent” or “EFIC”*

*EFIC allows research to begin before informed consent is obtained.*

*Is closely supervised by local research committees (IRBs)*

**19. EFIC can only be used when:**

*Emergency Research procedures can only be used when:*

* *The study might help the person, AND*
* *The person’s life is at risk, and*
* *The best treatment is not known, AND*
* *It is not possible to get permission either from the person (because of his or her medical condition) or, from the person’s family (because the medical condition needs to be treated very quickly)*

**20. The Emergency Research Procedures for ESETT:**

* *All patients having seizures in the emergency department will immediately be given the usual treatment for seizures– a drug like valium.*
* *If the first drug does not stop the seizure, ESETT patients will be treated next with one of the study medications.*
* *Patients having seizures will not be able to give consent*
  + *They are not awake*
  + *They need emergency treatment so there is not time to consent a parent or legal guardian.*

**21. What happens next?**

*If the seizure does not stop after the study medicine is given, the doctors treating the patient will follow the usual steps to give more medication to make the seizure stop. This is not part of the study.*

*Once the patient is treated and there is time to talk with a parent or guardian, he, she, or they will be asked for permission for their child to continue in the study*

*If the parent gives permission, the study team will monitor the patient until leaving the hospital.*

*If the patient is older than 6, and when the patient is able, he or she will be told about the study and be asked for permission to continue with the study monitoring.*

**22. What if a person does not want to be in the study?**

*If someone does not want to participate in ESETT they do not have to be in the study. Status epilepticus patients not in the study will receive the standard medical treatment for their seizures used by doctors in their community.*

*Because doctors must act quickly to treat the seizure, and because a patient cannot tell doctors their wishes during a seizure, the only way for a patient to let doctors know that they do not want to participate is to have their wishes noted on a medical alert tag or bracelet.*

*Doctors check these tags as part of their emergency evaluation. If the words “ESETT declined” are on the tag or bracelet, that patient will not be enrolled in the research.*

**23. What do you think about ESETT?**

*Now we would like to know what you think about the ESETT study. The study has not started yet, so…*

* *We want to hear what you think about it*
* *Do you think it is okay to do this study?*

*Before the study starts, the study team and the local research review board will consider your opinions before we decide if it’s okay to do the study in our community.*

*PLEASE BE SURE TO CLICK ON THE LINK TO TAKE THE SURVEY*

*Thank you so much for your time in participating.*