



Study Title: The Prevention and Risk Identification of SUDEP (Sudden Unexpected Death in Epilepsy) Mortality **PRISM** Project.

Person in Charge: Samden Lhatoo, MD

ASSENT FORM FOR 7 TO 13 YEAR OLD CHILDREN

What is a research study?

A research study is a way to find out new information about something. Kids like you do not need to be in a research study if you don't want to.

Why are you being asked to be part of this research study?

You are being asked to take part in this research study because we are trying to learn more about epilepsy. We want you to be in the study because you have epilepsy. Epilepsy is when people have times where they lose control of their bodies. This happens because of something about how their brains work. About 25 children like you will be in this study in the same way that you are. About 300 children like you with epilepsy will have information about them looked at by the doctors but won't be seen at the hospital.

Why is the study being done?

The results of the study will help us to understand what is different about people who die from epilepsy.

If you join the study what will happen to you?

We want to tell you about some things that will happen to you if you are in this study.

Today we would like to get a sample of your blood to see what about it is like or different from other people with epilepsy.

Your doctor may decide that it is a good idea to have you come to the hospital and stay for tests for a few days. **This would be true whether or not you are in this study.**

When you come to the hospital you will stay in a room and have some stickers with wires attached to you. These will let the doctor see more about how your head and body are acting. The doctor will also do a lot of tests. This will help the doctor understand how your body is working. Other than taking a little bit of blood, none of the measurements will hurt. There will be a camera in the room to record you in case you have a seizure. This camera would record your face unless you say you don't



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want this to happen. You might get a little bored, but there will be people to talk to and play with if you do get bored.

The second visit will not happen until you have a seizure. Once this happens, the doctors will want you to come to the hospital as fast as you can. The doctors will want to do pretty much exactly the same tests they did the first time. They will do the same tests to try to see what the seizure did and if anything has changed.

Almost always these two visits will be enough for the doctors. Sometimes, it will not be enough and the doctors will ask you to come back for another visit. If you don't want to do this, you can say no.

Only two things will be different about these visits if you are in this study.

- 1) you will have a small amount of blood and urine taken and
- 2) the information the doctors collect about you will be seen by more people.

If you decide this is not ok, you can say no to either one of these two things.

Being in this study does not mean you will be given any special medicine. The doctor will give you the same medicine whether or not you are in this study.

We believe this study will last for 3-6 years. It is possible we will want it to last longer, but this would not mean any more work from you.

We will use a needle to take some blood from your arm up to 3 times.

Will any part of the study hurt?

We will draw blood from a vein in your arm up to 2 times. You will feel a pinch when we use the needle to get the blood and this could leave a black and blue spot on the skin where the needle touched your skin.

Will the study help you?

Being in this study will not make you get better. We don't know if we will learn anything that will help children like you.

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IRB NUMBER: 11-11-27
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Will the study help others?

This study might find out things that will help other children with epilepsy some day.

Do my parents know about this study?

This study was explained to your parents and they said that we could ask you if you want to be in it. You can talk this over with them before you decide.

Who will see the information collected about you?

The things the doctors learn about you during this study will be kept safely locked up. Nobody will know it except the people doing the research.

Most of the study information about you will not be given to your parents. If we learn anything that could help you or help prevent a problem we will tell your parents. It is up to your parents whether to tell your teachers anything that we learn.

What do you get for being in the study?

You and your parents will not be paid for being in this study.

Will it cost anything to be in the study?

It will not cost you or your parents any money if you join the study.

Do you have to be in the study?

You do not have to be in the study. No one will be upset if you don't want to do this study. If you don't want to be in this study, you just have to tell us. It's up to you.

You can also take more time to think about being in the study. You don't have to choose now.

What if I have any questions?

You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call the doctor at (216)844-5855.

You can also take more time to think about being in the study and also talk some more with your parents about being in the study.

What choices do you have if you say no to this study?

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This study is extra, so if you don't want to do it nothing else will change.

Other information about the study.

If you decide to be in the study, please write your name below.

You can change your mind and stop being part of it at any time. All you have to do is tell the doctor or your parents that you don't want to do it.

You will be given a copy of this paper to keep.

Write your name

Witness

Date