

Title: Diabetic Ketoacidosis and its Impact on Neurocognition

Assent Form

Your mom or dad would like you to participate in this research study. Before you decide whether you want to be in it, we want to tell you about it so you can ask any questions. A research study is something like a science project at school but harder to do. When doctors want to learn more about how to help kids, they do a research study.

1. What will happen to me in this study?

If you want to be in the study then the following will happen:

- You may have to come to Stanford Medical Center or during your visit to the diabetes clinic you will be asked to answer some questions that are like what you may have to do at school or for homework, for example: look at pictures, draw, write, spell, count, or follow directions. If you feel upset about a question you do not have to answer it.
- You will be asked to answer these questions again
- It may take about 20 minutes to 2-4 hours to answer the questions.
- You will see a sample Magnetic Resonance Imaging or MRI machine. The research people will tell you about the machine and ask you to lie down in it and listen to the sounds the machine makes when it is taking a picture. This machine will create special pictures of the brain.
- You will watch a videotape of the MRI machine so that you can see how it works and hear what sounds it makes.
- You will come back on another day to have the MRI machine take a picture of your head. You will get a locker to store your things . You may need to lie in the machine for up to 1 hour. You may wear headphones to listen to music, watch a video, or take a nap.
- You may be asked to answer the questions and have the MRI machine take a picture of your head again in 1 year.

2. Can anything bad happen to me?

Taking part in a research study involves some risks. The most likely risks of this study are listed below. This study may include risks that we don't know about at this time.

MRI Scan of the Head: This machine will create special pictures of the brain using magnets. You will hear loud noises. The machine is not harmful. The

hardest part of the scan is lying still for up to 1 hour. There is not a lot of room in the machine and you may feel very crowded. If, for any reason, you feel this makes you feel upset or scared the machine can be stopped at any time.

3. Can anything good happen to me?

The doctors can learn about how having diabetes and not enough insulin for a long time can affect the brain and learning.

4. Do I have other choices?

You do not have to participate if you do not want to.

5. Will anyone know I am in the study?

We will not use your name. You will be given a code number. No one outside of Stanford will know you are part of the study.

6. What happens if I get hurt?

The research people will help you find medical care but this study does not provide money for medical or other costs.

7. Who can I talk to about the study?

If you get hurt while taking part in this study please call Tandy Aye, MD 650-723-5791 or Kim Caswell, APRN, BC at 650-724-1201.

If you have questions about the study but want to talk to someone else who is not a part of the study, you can call the Stanford Institutional Review Board (IRB) at (650-723-5244 or toll free at 1-866-680-2906.

8. What if I do not want to do this?

You can stop being in the study at any time without getting in trouble. Your doctor will continue to see you for your regular visits.

SIGNATURE CLAUSE

If you are not happy about this study or if you have any questions, you can ask a grown up to help you call the Stanford Institutional Review Board (IRB) to speak to someone other than your doctor at (650)-723-5244 or toll free at 1-866-680-2906 or write the Stanford IRB, Administrative Panels Office, Stanford University, Stanford, CA 94305-5401.

SIGNATURE

If you agree to be in this study please sign here.

Signature of Child

Date