Documentation of Assent from Pediatric Subjects

Title: The ability of Kuvan® to prevent meal-induced lipid peroxidation and endothelial dysfunction in patients with phenylketonuria: a pilot study

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Subject age: ________ years.

For subjects in this study who are minors, one of the following Pediatric Assent sections must be satisfied. Place a checkmark beside the method used.

1. _____ (<6 years) NO ASSENT REQUIRED

2. _____ (ages 6-10) VERBAL ASSENT
The study and the treatment have been explained to this child in an age-appropriate manner. The child has asked questions, verbalizes understanding of the information, and provides verbal assent.

__________________________________  ____________________
Person Soliciting Assent                   Date              Time

3. _____ (ages 11-16) WRITTEN ASSENT See attached Written Assent document.

4. _____ (age 17) READ/SIGN MAIN CONSENT DOCUMENT WITH GUARDIAN

5. _____ (any age) UNABLE TO PROVIDE ASSENT

In my opinion, this child cannot give informed assent.

Reason(s): ______________________________________________________

__________________________________  ____________________
Person Soliciting Assent                   Date              Time

Principal Investigator                  Date              Time

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WRITTEN ASSENT DOCUMENT

We are asking you to volunteer to be in a medical research study. You are being asked to participate because you are healthy and close in age to a person we are studying who has a disorder called phenylketonuria (PKU). In this study, we are looking at how markers in your blood change after eating a meal that has fat and sugar. We will take about 2 tablespoons of your blood before eat the specially designed meal and just under ½ a tablespoon every other hour for 6 hours after you eat this specially designed meal. Also, we will look at how your arm blood vessels react to this meal, both before and after you eat it.

First we will ask your parent/legal guardian questions about your health. We will then have our study doctor give you a physical examination. During the physical examination, we will ask for blood and urine samples to make sure you’re healthy enough to participate. If you are, we will ask you to attend 1 study visit. Information from this study visit will help us understand how the drug Kuvan® affects blood markers and blood vessels in patients with PKU. You will not be asked to take the drug.

There are some parts of the study that you may feel a little pain or discomfort. We will have to take blood through a needle. To make this less painful, we will place a special needle system once and leave it there until your study visit is over. Also, we will be testing your blood vessels in your arm. This will require us to squeeze your arm tight with a blood pressure cuff for 5 minutes at two different time points during each study visit. The person performing the test may have to repeat the measurement 3 times on each occasion to make sure we have a good reading. Your arm might feel tingly, like it has gone to sleep. After the test, though, your arm will begin to feel normal again.

You can refuse (say no) to be in this study. Your doctors or your parents cannot make you be in the study if you don't want to be in it. If you agree to be in the study but change your mind about it later, you can stop being in the study.

Your doctor and/or a study team member will talk to you about what it means to be in a research study. You should ask your doctor and/or a study team member all of the questions you have. You should also talk to your parents about the study.

If you agree to be in the study, sign here:

_________________________________  __________________________  __________________________
Participant                        Date              Time