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Official Title of Study: Pilot study of at-home ammonia monitoring in patients with an inborn error of ammonia metabolism

NCT: NCT06953505

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OREGON
HEALTH & SCIENCE
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Child Assent Form

IRB# 00025898

TITLE: Pilot study of at-home ammonia monitoring in patients with an inborn error of ammonia metabolism

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PURPOSE:

This study is to learn more about using an at-home device every day to measure your blood ammonia levels from a finger poke.

PROCEDURES:

This study will last about a year, and during this time you will need to come for at least 3 study visits, which may last a few hours. At the study visits, we will ask you some questions, we will teach you and your parents/guardians how to use the device, and we will ask for you to get a blood draw.

At home every day, your parents or guardians will help you measure your ammonia levels daily using the at-home device. You will need to provide a small drop of blood each day for this. Your parents or guardians will also help us write down some daily information about your health, including how you are feeling, your temperature, your pulse, and other health measurements.

RISKS:

You may feel pain from the blood draws and the daily finger poke. You may feel scared or anxious about the pain from the blood draws or finger poke.

This research study was explained to me. I know how it may or may not help me. I also know that this study will help doctors learn more about daily ammonia levels for people with my condition. To be sure that I know what is going to happen, the investigator will ask me the

following:

1. To explain what I will do and what will happen in this study.
2. If I have any questions or want to know anything else about this study or (about my genetic condition.
3. To explain some of the good and bad things that might happen to me if I enter this study.

I have thought about being a part of this study. I have asked and received answers to my questions. I agree to be in this study. I know that I don't have to agree to be in the study. Even though I agree to be in it now, I know I may feel differently later on and can ask to stop being in the study. I know that I may talk with my parents and/or doctor about not being in this study at any time.

Name/signature: _____

Date: _____