

**EMORY UNIVERSITY/CHILDREN’S HEALTHCARE OF ATLANTA  
ASSENT FORM FOR MINOR SUBJECTS**

**Study Title:** Educational, Social Support, and Nutritional Interventions and Their Cumulative Effect on Pregnancy Outcomes and Quality of Life in Teen and Adult Women with Inborn Errors of Metabolism.

**Principal Investigator:** Rani H. Singh, PhD, RD, LD; Department of Human Genetics

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This page to be filled out by research team at time assent is obtained:

**Subject’s Age:** \_\_\_\_\_years (If the child is **younger than 6 years old**, assent is not required.)

**Subject’s Name:** \_\_\_\_\_

**Check one box:**

**This child is 11 to 17 years old** — must obtain subject’s signature on page 2 of assent form to document assent

In my opinion, this child is unable to provide informed assent for non-age-related reasons, and the PI for this study has been informed of this determination.

• Reason(s): \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

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Signature of person soliciting assent (if above box is checked)      Date      Time

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**Introduction/Purpose:** We are asking you to volunteer for a research study because you are a female with an inborn error of metabolism. In the Metabolic Camp Study, we are studying the effectiveness of teaching young women with inborn errors of metabolism about nutrition, their disorder, and planning for a healthy pregnancy.

**Study Procedures**

- We may take a picture of your bones to let us know how your bones are growing and how strong they are. This test is called DXA.
- We may measure your body composition using a process called bioelectrical impedance. This requires you to stand on a small scale for 5 minutes.
- We may also collect a urine sample from you to test an at-home urine phe monitor.
- We may collect extra blood for tests that will tell us more about your nutrition and health as someone with PKU or MSUD.
- We may additionally collect a stool sample so that we can learn about the bacteria in your gut and how it relates to PKU.
- We may complete genetic testing to find out more information about why you have PKU or MSUD.
- We may ask you to discuss your thoughts about having PKU or MSUD in a small group and/or by questionnaire.
- In addition, we may give you a pregnancy test and ask you to share information about your pregnancy if you are pregnant or become pregnant in the future. You may not want to do some of the things listed and that's okay.

**Risks**

When blood is taken from your arm or hand it can hurt a little and leave a little black and blue mark that will quickly go away. You may feel nervous during some of the tests and when answering questions. There is a small chance of the loss of privacy. Your doctors and study staff will take all necessary actions to prevent these events from occurring. When you have your bone density test (DXA Scan), you will be exposed to a small amount of X-ray radiation. The DXA scan cannot be done if you are pregnant. The main risk associated with a radiation dose to you or the fetus is the possibility of developing cancer from the radiation later in life. The risk for this cancer from this study is very slight. There may be other effects of DXA scans on your health which we do not know about at this time. These procedures are not necessary for your medical care and will occur because you participate in this study. There may be other things that can happen which we do not know about at this time.

