



Urea Cycle Disorders, Nutrition & Immunity

A clinical research study at the National Institutes of Health

“The goal of our study is to learn about the dietary complications in patients with urea cycle disorders (UCD) and understand the effects that those complications may have on the function of the immune system”.

*Peter J. McGuire, MS, MBBCh
Principal Investigator*

Who can participate?

To join the NIH UNI Study a person must:

- Be at least 2 years of age
- Have a biochemically confirmed UCD or related disorder
- Be able to travel to and be admitted to the National Institutes of Health (NIH) Clinical Center in Bethesda, Maryland for 2 separate visits about 2-3 months apart

There are some reasons why someone may not be able to join the study. For details, please see our Web site: <http://www.genome.gov/uni>

Other important information:

What is the cost of the study?

- The visits and all testing are free and there is no cost to you, your family, or your insurance company for participating in this study.

What about travel?

- If you live locally (near the NIH) we will give you some money for meals and provide lodging if necessary. If you live further away, we will pay for your transportation to NIH (plane, care mileage, train, etc), lodging, and give you some money for meals. The NIH must arrange all travel.

Will I (my child) get paid for joining the study?

- No, participants in the study will not receive any compensation other than some food, travel and lodging expenses.

What is involved in the study?

We will review your (your child's) eligibility for the study with you on the phone. We may ask to review outside medical records.

Study participants will travel to the NIH Clinical Center for at least 2 visits. The first visit lasts for 2-3 days & the second visit typically lasts 2 days.

You (your child) will meet with a geneticist to review your medical & family history and for a physical exam. We will ask you (your child) to allow us to collect urine, draw blood, and perform a detailed nutritional & immunologic assessment.

We will suggest an additional set of evaluations for some participants that we feel is appropriate based on age & level of independence. We will explain the need for those studies to you (your child).

We will offer the seasonal/H1N1 influenza vaccine that is recommended for all UCD patients.

At the 2-3 month follow up visit we will determine whether or not your (your child's) immune system was able to respond to the vaccine. You will receive the results of your (your child's) clinical testing.



For more information about the study please visit our Web site:

<http://www.genome.gov/uni>

or contact our study coordinator by phone at (301) 451-9145

or by email at unistudy@mail.nih.gov

