

# CHILDREN'S NATIONAL MEDICAL CENTER

Center for Genetic Medicine, Children's Research Institute  
111 Michigan Avenue, NW  
Washington, DC 20010  
(202) 476-6011

## ASSENT (AGES 7 through 11) TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

### Patient with a leukodystrophy

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**TITLE OF STUDY:** New Diagnostic Approaches In Leukodystrophy

**PRINCIPAL INVESTIGATOR:** Adeline Vanderver, MD; Department of Neurology

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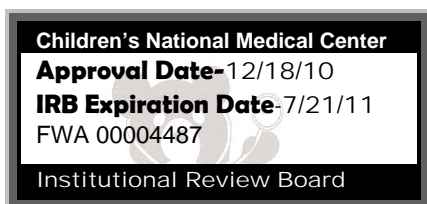
#### A & B. WHAT IS THE REASON FOR THE STUDY AND WHAT WILL HAPPEN IN THE STUDY?

1. Participating in this research study means that you allow us to study blood samples, urine samples, spinal fluid samples and skin cells sent to us by your doctor to try to find why you are sick. It may also mean that you get a blood sample taken just to send to Dr Vanderver. It may also mean that you will come to Children's National Medical Center to see Dr. Vanderver. She may examine you just like your doctors and recommend tests.
2. Researchers in a laboratory will look at your genes (made up of DNA) and proteins to see if there is a change that may be responsible for some of your health problems. Genes are the recipes for how our body works and the DNA are the words/letters that make up this recipe. A protein carries out the instructions of the recipe and is made up from the recipe.
3. The laboratory will use these studies to try to find out why kids like you are having health problems like having a hard time moving your muscles or having to be in the hospital and to try to make better tests for these problems.

#### C. WHAT POSSIBLE UNEXPECTED THINGS COULD HAPPEN?

You may feel upset and sad because you are not feeling well, and because the doctors are doing tests to find out what is making you have health problems. If you are upset, you should talk to your parents about this and they may bring you to the doctor to talk about your feelings.

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**D. WHAT POSSIBLE GOOD THINGS COULD HAPPEN?**

By having samples from individuals with genetic disorders and their family members, our laboratory has made discoveries about genes and proteins that have added to our understanding of the genetic conditions and may allow treatment in the future. It may also mean that your doctor gets a specific answer to what is making you have problems with your health.

**ASSENT**

I understand what the doctor has told me and I want to be in the study.

Printed Name of Participant: \_\_\_\_\_

Medical Record Number: \_\_\_\_\_

Signature of Participant: \_\_\_\_\_

**Witness (to signature):** \_\_\_\_\_ **Date:** \_\_\_\_\_  
(may be investigator)

Translator's Signature (if, applicable): \_\_\_\_\_ **Date:** \_\_\_\_\_  
Language: \_\_\_\_\_

**AFFIDAVIT OF PERSON OBTAINING ASSENT:** I certify that I have explained to the above individual(s) the nature and purpose of the study, potential benefits, and possible risks associated with participation in this study. I have answered any questions that have been raised.

Printed Name of Individual Obtaining Assent: \_\_\_\_\_

Title: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

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