

CHILDREN'S NATIONAL MEDICAL CENTER

Center for Genetic Medicine, Children's Research Institute
111 Michigan Avenue, NW
Washington, DC 20010
(202) 884-6065

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

Patient with a leukodystrophy

TITLE OF STUDY: New Diagnostic Approaches In Leukodystrophy

PRINCIPAL INVESTIGATOR: Adeline Vanderver, MD; Department of Neurology

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, 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 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 sick and to try to make better tests for these disorders.

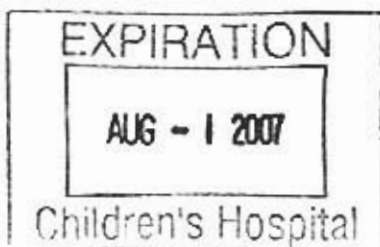
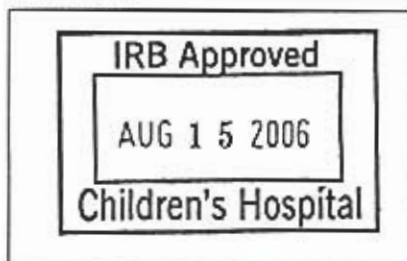
C. WHAT POSSIBLE UNEXPECTED THINGS COULD HAPPEN?

You may feel upset and sad because you are feeling sick, and because the doctors are doing tests to find out what is making you sick. 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.

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.

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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)

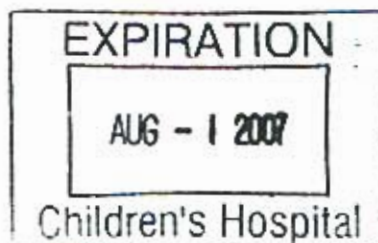
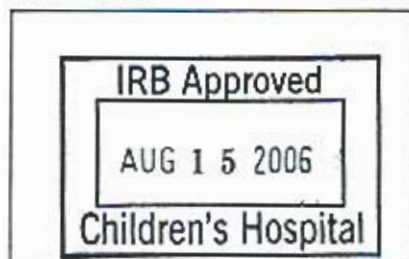
Translator's Signature (if, applicable): _____ Date: _____
Language: _____

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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