

# CHILDREN'S NATIONAL MEDICAL CENTER

Center of Translational Science  
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Washington, DC 20010  
(202) 476-6439

## ASSENT (AGES 12 to 17) TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

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<b>TITLE OF STUDY:</b>	<b>Core A: The Hepato-Renal Fibrocystic Diseases Translational Resource Collaboration with University of Alabama at Birmingham</b>
<b>PRINCIPAL INVESTIGATOR:</b>	<b>Lisa Guay-Woodford, MD</b>

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**INTRODUCTION:** We would like to invite you to be part of a research study at Children's National Medical Center. Before you decide if you would like to participate, we want you to know why we are doing the study. We also want you to know about any risks (anything unexpected that might happen) and what you will be expected to do in the study. You can only be in the study if your parent(s) agree(s).

This form gives you information about the study. Your doctor or a research staff member will talk to you about the study and answer any questions you have. We encourage you to discuss this study with your family before making your decision. We will ask you to sign this form to show that you understand the study. We will give you a copy of this form to keep. It is important that you know:

- You do not have to join the study;
- You may change your mind and stop being in the study any time you want and no one will mind. In some cases however, stopping the study medication early may cause harm to you. Your doctor will discuss this with you;
- If we make any important change to the study we will tell you about it and make sure you still want to be in the study.

### A. WHAT IS THE REASON FOR THE STUDY?

This Children's National Medical Center study (Pro00003209) is working with staff at the University of Alabama, Birmingham (UAB) who have a center where they store tissue for research. The Children's National Medical Center has partnered with UAB is to make it easier for researchers to obtain rare resources such as liver and kidney liver tissue from hepato-renal fibrocystic disease patients to help further our knowledge about these diseases.

You are invited to be in the study because you or your child has a hepato-renal fibrocystic kidney disease and will be having kidney or liver tissue removed OR your child has had/is scheduled to have an autopsy. This study would like to collect the tissue and store it in at the UAB tissue bank for future research.

## **B. WHAT WILL HAPPEN IN THE STUDY?**

If you choose to participate, you will sign this consent form and will provide the information of the doctor where you will be having the kidney or liver tissue removed or where the autopsy will be performed. This doctor will collect tissue samples. Children's National Medical Center will send all of the materials that will be needed to your doctor including: a mailer that is addressed to the UAB Tissue Repository, a tissue collection kit, and instructions on how to collect and store the tissue. These tissue samples will be labeled with an identifier that is unique to you and will be sent to UAB to process and store.

When researchers are interested in getting tissue for their investigations, they will contact Dr. Lisa Guay-Woodford and will fill out a request form that will be then be reviewed by the Core A Scientific Advisory Committee. This Committee will determine whether to grant permission for tissue samples to be released from the tissue bank for specific research studies.

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

This study will involve gathering a limited amount of information from patients and parents. This information will include the patient's diagnosis and age at diagnosis as well as the patient and parent names and your contact information. This information will be assigned a unique identifier number and your Personal Health Information will be held in the strictest confidence. Only the investigator, Dr. Lisa Guay-Woodford, and her study coordinator, Elena Gibson will have access to your name. The information that you supply will be added to our database and referred to by a unique identifier number instead of your name.

There are no risks to tissue collection since tissue will be collected after a nephrectomy or hepatectomy or during an autopsy.

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

There is no direct benefit to you or your family if you choose to participate. The reason for this study is to learn more about the clinical factors that affect the clinical course of the liver or kidney fibrocystic diseases.

There is a possibility that results from this protocol may provide important new insights for the future care of people.

## **E. WHAT OTHER CHOICES DO YOU HAVE IF YOU DO NOT WANT TO BE IN THE STUDY**

The alternative is to not participate.

## F. HOW WILL WE KEEP YOUR RECORDS PRIVATE?

We will keep the records of this study confidential. Only the people working on the study will know your name. They will keep this information in case we have to find you later to let you know of any new information that may affect your health.

## ASSENT

By signing this form, you agree that you have talked to your doctor about the study and understand it, and want to be in the study. You also agree that you have been told about the risks (unexpected things) and benefits (good things) of the study, and about other choices. You may stop being in the study at any time and no one will mind and nothing will change about your medical care other than not being in the study. Please call the Principal Investigator, [Lisa M. Guay-Woodford](#), at 202-476-6439 if you have any questions.

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: \_\_\_\_\_