CHILDREN'S NATIONAL MEDICAL CENTER

Center of Translational Science
111 Michigan Avenue, NW
Washington, DC 20010
(202) 476-6439

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

TITLE OF STUDY:	**Core A: The Hepato/Renal Fibrocystic Diseases Translational Resource**
PRINCIPAL INVESTIGATOR:	**Lisa Guay-Woodford, MD**
IRBEAR PROTOCOL:	**Pro00003209**

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 study 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.
- 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?

The purpose of this study is to gather more information on Autosomal Recessive Polycystic Kidney Disease (ARPKD) and other hepato/renal fibrocystic diseases. These diseases are rare genetic conditions that affect both children and adults. Abnormal growths grow in the kidneys and damage the liver. We want to know more about these diseases. What we learn about these diseases will be used to develop a web based resource so that anyone can learn more about ARPKD or other hepato/renal fibrocystic diseases.

You are being asked to participate in this study because you have been diagnosed with a hepato/renal fibrocystic disease.

B. WHAT WILL HAPPEN IN THE STUDY?

If you choose to be in this study, we will ask you to sign a form to allow the study team to see your past, current, and future (for the length of this study) medical health information. When we receive your information, we will remove your name or any other identifiable health information from your received records and enter your clinical data into the Hepato/Renal Fibrocystic Diseases clinical database.

Being in this study does not require you to visit our center.

We will ask for your medical information since the time of the diagnosis of your disease going forward. Some information that we could collect, would be clinic notes, lab results, and physician consult reports. There will be initial data entry and follow up data entries lasting for the duration of this study or until you want to stop participating in this study. This study does not involve any medications. You do not have to come see us at the hospital. We collect clinical information only when you have scheduled clinic/outpatient or inpatient hospital visits.

If you choose to participate in the optional genetic material testing portion of the study, we will send a mailer and a blood collection kit to the doctor of your choice. You will then have blood collected (~5 mL or a teaspoon). When the doctor you specify obtains the blood samples, these samples will be sent to Children's National Medical Center and each sample will be processed to get the DNA. These DNA samples will be labeled only with an identifier that is unique to you and stored in the Clinical Studies Resource BioRepository of the Clinical and Translational Science Institute at Children's National. They will be tested to search for a genetic basis for ARPKD. As recommended by the National Institutes of Health, the sequences (without your name or any further identifier) will be submitted to national databases to facilitate research into genetic causes of conditions.

We will ask you to drop out of this study if:

- We have not been able to get medical information from you/your doctors.
- Your diagnosis of ARPKD or another hepato/renal fibrocystic disease is not verified.

C. WHAT POSSIBLE UNEXPECTED THINGS COULD HAPPEN?

There will be no physical harm to you for being in this study. However, it is possible that someone who is not part of the study could get personal information about you. We will do what we can to make sure that doesn't happen.

If you choose to participate in the optional genetic material portion of the study, there are some minor risks that may be associated with blood collection including discomfort from the needle stick, bruising, fainting, weakness and rarely infection at the site.

D. WHAT POSSIBLE GOOD THINGS COULD HAPPEN?

You will not benefit from being in this study. The reason for this study is to learn more about the factors that affect the disease in people with hepato/renal fibrocystic diseases.

There is a possibility that results from this protocol may provide important insight for the future care of people with these diseases.

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

The other choice is to not be in this study. If you choose not to be in the study, your care will not change.

F. HOW WILL WE KEEP YOUR RECORDS PRIVATE?

We will keep the records of this study private. 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 study 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, MD, at 202-476-6439 if you have any questions.

Printed Name of Participant: _____Date:_____

Medical Record Number: _____Date:_____

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: _____