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 want to tell you about a research study at Children's National Medical Center that involves the disease that you have. We want to tell you 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).

We will talk to you about the study and answer any questions you have. After you talk to us, please talk with your family about this study before you decide about whether to join the study. 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?

We want to know more about Autosomal Recessive Polycystic Kidney Disease (ARPKD) and other hepato-renal fibrocystic diseases. These diseases are rare inherited conditions that affect both children and adults. The tubes that make up the kidney and the liver do not form normally and with time, these abnormalities lead to scarring. We want to know more about these diseases and share this information with other families and their doctors.

We are asking you to join this study because you have been diagnosed with ARPKD or one of the other hepato-renal fibrocystic diseases.

In this Children's National Medical Center study (Pro00003209), we are working with Duke University (**Study Title: Duke Task Force for Neonatal Genomics: Genome and Exome Sequencing and Return of Results)** to better understand the inherited problem in this set of disorders. Genetic material (DNA) for these studies can be obtained from a blood sample. For these studies, we need a blood sample from you and your parents.

B. WHAT WILL HAPPEN IN THE STUDY?

If you choose to be in this study, you will sign this form and your parents will give us the information about the doctor who you would like to collect your blood samples. Children's National Medical Center will send a blood collection kit to the doctor you choose and they will collect your blood (8.5 mL or about one and a half teaspoons). These blood samples will be sent to Children's National Medical Center and will be processed to obtain DNA.

If you choose to be contacted by the Duke study team, we will send them the information about how to contact you. After you speak with the Duke study team, you may choose to sign their Assent form, saying you want to participate in the Duke University genetic studies. Once the Duke study team lets us know that you have signed their Assent form, Children's National Medical Center will send your DNA to Duke University for genetic analyses.

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.

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?

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 and genetic factors that affect the clinical course of the hepato-renal fibrocystic diseases. The clinical report of your genetic results will be discussed with you and your family. .

There is a possibility that results from this study may provide important new insights 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: _____
Medical Record Number: _____

Signature of Participant: _____

Witness (to signature): _____Date:_____
(may be investigator)

Duke Task Force for Neonatal Genomics: Genome and Exome Sequencing and Return of Results Study:
Please tell us whether or not you would like to be contacted by the Duke University Study team.
If you select "yes", we will send the Duke University Study team your contact information. They will contact you to tell you about their study and go over their Assent form with you.
If you select "No", we will not send the Duke University Study team any of your contact information.

☐ Yes, I give my permission to the Duke University Study team to contact me
☐ No, I do not give my permission to the Duke University Study team to contact me

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: _____