CHILDREN'S NATIONAL MEDICAL CENTER

Center of Translational Science
111 Michigan Avenue, NW
Washington, DC 20010
(202) 476-5000

Consent/Parental Permission for Collection of Samples and Health Information for Research

Title of Study: Core A: The Hepato-Renal Fibrocystic Diseases Translational Resource Collaboration with University of Alabama at Birmingham

Principal Investigator: Lisa Guay-Woodford, MD

Throughout this document, "You" always refers to the person (you or your child) who takes part in the study.

We are inviting you to be part of a research study at Children's National Medical Center (Children's National). 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 and what you will be expected to do in the study.

This form gives you information about the study. Your study doctor or a member of the research team will talk to you about the study and answer all of your questions. We encourage you to discuss this study with your family and anyone else you trust before making your decision. You must sign this form if you agree to take part in the study. We will give you a signed copy of this form to keep.

Your participation in this research study is voluntary

There will be no penalty or loss of benefits to which you are otherwise entitled if you decide not to be in the study or withdraw from the study later.

This means that:

- You do not have to join the study.
- You may change your mind and stop being in the study at any time.

- We will tell you if we make any important changes to the study so that you can decide if you still want to be in the study.
- We will tell you about any important new findings that develop during the research which may affect your willingness to continue participating.

Why is this Research Study Being Done?

This Children's National Medical Center study (Pro00003209) is being conducted in collaboration with colleagues at the University of Alabama, Birmingham (UAB) who have a well established and experienced tissue repository or tissue bank that stores tissue for research. The purpose of this collaboration 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 Repository for future research.

What Will Happen in this Research 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 University of Alabama, Birmingham, 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 the UAB Tissue Repository 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.

How Long Will My Participation in the Research Study Last?

There is no scheduled date on which your samples will be destroyed. Your samples may be stored for research until they are "used up."

What Are the Risks and Possible Discomforts from Being in this Research Study?

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.

What Are the Possible Benefits from Being in this Research Study?

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 hepato-renal fibrocystic diseases.

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

How Will My Privacy Be Protected If I Take Part in this Study?
Who Will See the Information that I Give for the Research Study?

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. The federal government can review the study records and medical records to make sure we are following the law and protecting the children in the study. Your medical record is confidential, but just like any medical record; there are some exceptions under state and federal law.

Genetic Information Nondiscrimination Act (GINA)

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies may not request your genetic information that we get from this research
- Health insurance companies may not use your genetic information when deciding whether to insure you or the amount of money they will charge you.
- Employers may not use your genetic information that we get from this research when deciding to hire, promote, or fire you.

This new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Will it Cost Me Anything to Take Part in the Study?

There are no costs to you or to your insurance company for taking part in this study.

Will I Be Paid for Taking Part in this Study?

You will not receive compensation for taking part in this study, now or in the future. In particular, there are no plans to compensate you for any patents or discoveries or other products or intellectual property that may result from future research or commercialization efforts done using your tissue and information that are stored as part of this study. This includes your tissue and other information about you that, with your permission, Children's National and the researchers involved share with our research collaborators, such as other research institutes or drug, medical device, biotechnology or other research collaborators.

What Other Choices Do I Have if I Don't Want to Take Part in the Study?

If you do not want to participate in the study, there are no other choices except not to take part

Whom Can I Call if I Have Questions about this Research Study?

We want you to ask questions about any part of this research study at any time.

- For questions about the study or the information in this informed consent/parental permission document, call the Principal Investigator, Lisa Guay-Woodford, MD, in the Division of/Center for Translational Science at 202-476-6439.

Whom Can I Call if I Have Questions or Concerns about My Rights as a Research Study Participant?

The Children's National Office for the Protection of Human Subjects is available to talk with you about:

- Your rights as a research participant;
- Your concerns about the research;
- A complaint about the research

This is the administration office for the Institutional Review Board, which is a group of doctors, nurses, and non-medical people who review research studies for safety and the protection of people who participate in research. You can call the Office for the Protection of Human Subjects at 301-565-8452.

The National Institutes of Health supports a bilingual (English/Spanish) research participant and family advocate at Children's National. The advocate, Dr. Tomas Silber, is

here to answer your questions or concerns about taking part in this research. Dr. Silber does not work for the doctors who are doing this research and they do not pay him. He is here as a resource to assist you in terms of your participation during any research.

You may contact Dr. Silber at any time. This can be done before you decide to take part in the research, during the study, or even after you finish the study. You can call Dr. Silber at 202-476-3066 or reach him by e-mail at tsilber@childrensnational.org.

AUTHORIZATION TO USE YOUR INFORMATION
Your Decisions Regarding Use of Your Samples and Protected Health Information (PHI)

Banking of Tissue Specimens for Future Research:

We would like to store tissue specimens collected from you in this study in a tissue bank for future research as described below. The tissue specimens consist of liver, kidney, pancreas, lung, brain, heart and placental (from mother, if samples are collected from newborns). The University of Alabama, Birmingham Tissue Biorepository, maintains the tissue bank.

Your samples and information will be used by us mainly as collaboration with the University of Alabama, Birmingham for future research. The long-term goals of the research are to learn how to better understand, prevent, diagnose or treat hepato-renal fibrocystic kidney disease. It is not possible to list every research project. Also, we cannot predict all of the research questions that will be important over the next years. As we learn more, there are new research questions and new types of research related to hepato-renal fibrocystic kidney disease may be done.

Please indicate your approval of any or all of the following by initialing next to the statement:

- My tissue may be stored in the above named bank for future analysis related to this research study.

  ☐ Yes ☐ No Initials _____

- My tissue may be stored in the above named tissue bank for future analysis on hepato-renal fibrocystic kidney disease.

  ☐ Yes ☐ No Initials _____

Your samples and information may also be used by us for research on other conditions; for example, as comparisons to other diseases.

- My tissue may be stored in the above named tissue bank. Researchers may use the tissue for future studies that are not related to this study or the disease named above.

  ☐ Yes ☐ No Initials _____

- My tissue may be stored without any of my identifying information for use in other studies of other diseases.

  ☐ Yes ☐ No Initials _____

- I may change my mind at a later time and request that my tissue specimen be destroyed. If I change my mind and want to request that my tissue be destroyed, I must do so in writing to

  Lisa Guay-Woodford, MD
  Children's National Medical Center
  111 Michigan Ave NW,
  Washington DC, 20010

In the future, other researchers may want to use your samples in other similar studies that try to find out more about your specific kind of condition or other similar conditions. If you select yes below, you are authorizing Children's National and the researchers involved to share your samples with other researchers as an **anonymous** sample. This means that all information identifying you will be removed from the research data record.

We will careful review requests by other researchers before sharing your samples with them. The other researchers must have a high level of data security and protection in place before your samples will be shared.

It is important to understand that every reasonable effort will be made to protect participant anonymity but that DNA by its very nature can allow a determined individual to learn some of your identifying information. The research team at Children's National will carefully evaluate the use of DNA for such purposes and will consult with a research ethics team at Children's National before sharing any samples**.**

Please indicate your approval of the following by initialing next to the statement:

- I give my permission for anonymous samples and anonymous relevant health information to be shared with other researchers working on diseases related to my condition.

  ☐ Yes ☐ No Initials _____

You may change your mind at a later time and request that your tissue specimen(s) be destroyed. To request that your tissue be destroyed, you must do so in writing to

Lisa Guay-Woodford, MD
Children's National Medical Center
111 Michigan Ave NW,
Washington DC, 20010

In 1996 the government passed a law known as The Health Insurance Portability and Accountability Act (HIPAA). This privacy law protects your individually identifiable health information (Protected Health Information or PHI). The privacy law requires you to sign an agreement so researchers can use or share your PHI for research purposes. This describes to you how information about you may be used or shared if you are in a research study. It is important that you read this carefully and ask a member of the research team to explain anything you do not understand.

I authorize the Principal Investigator, Lisa Guay-Woodford, MD and her research staff to create, access, use, and disclose my PHI for the purposes described below.

Protected Health Information that may be used and shared includes:

☒ Information that identifies you such as date of birth, and diagnosis

The Researchers may use and share my Protected Health Information with:

- The Principal Investigator, other Investigators, Study Coordinators, and all administrative staff in charge of doing work for the study;
- Government agencies that have the right to see or review your PHI including, but not limited to, the Office of Human Research Protections and the Food and Drug Administration;
- Children's National Medical Center Institutional Review Board (the ethics board that reviewed and approved this research study);
- Audit Committee of the Children's National Medical Center Institutional Review Board;
- Quality Improvement Program Coordinator and other staff in the Office for the Protection of Human Subjects at Children's National Medical Center.

In addition to the above people and organizations, the Researchers may also use and share my Protected Health Information with:

☒ Any other outside entity who will receive health information
Please list: The University of Alabama, Birmingham

Also, your primary physician will be contacted if during the course of the study the researcher learns of a medical condition that needs immediate attention.

Should your health information be disclosed to anyone outside of the study, your information may no longer be protected by HIPAA and this Authorization. However, the use of your health information will still be regulated by applicable federal and state laws.

Storage of PHI in a Database:

We would like to store personal health information collected from you in this study in a database for future research. We plan to store personal health information collected from you in this study in a Research Electronic Data Capture (REDCap) database is maintained at Children's National Medical Center.

Please indicate your approval of any or all of the following by initialing next to the statement:

- My personal health information may be stored in the above named database for future analysis related to this study.

  ☐ Yes ☐ No Initials _____

- My personal health information may be stored in the above named database for future analysis related to [insert name of specific study].

  ☐ Yes ☐ No Initials _____

- My personal health information may be stored in the above named database. Researchers may contact me to request my authorization for future studies that are not related to this study or the disease named above.

  ☐ Yes ☐ No Initials _____

- My personal health information may be stored without any of my identifying information for use in other studies of other diseases.

  ☐ Yes ☐ No Initials _____

If you agree to participate in this research study, the research team, the research sponsor (when applicable) and the sponsor's representatives may use Personally Unidentified Study Data. The Personally Unidentified Study Data does not include your name, address, telephone, or social security number. Instead, the researcher assigns a code to the Personally Unidentified Study Data. Personally Unidentified Study Data may include your date of birth, initials, and dates you received medical care. Personally Unidentified Study

Data may also include the health information used, created, or collected in the research study. The research team or the research sponsor may share the Personally Unidentified Study Data with others to perform additional research, place it into research databases, share it with researchers in the U.S. or other countries, or use it to improve the design of future studies. They may also publish it in scientific journals, or share it with business partners of the sponsor and to file applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

You do not have to sign this Consent/Authorization. If you decide not to sign the Authorization, you will not be allowed to participate in the research study.

After signing the Consent/Authorization, you can change your mind and:

- Revoke this Authorization. If you revoke the Authorization, you will send a written letter to Lisa Guay-Woodford, MD to inform her of your decision.
- If you revoke this Authorization, researchers may only use and disclose the PHI that was collected for this research study before you revoked the Authorization.
- If you revoke this Authorization, your PHI may still be used and disclosed if you should have an adverse event (unexpected side effect).
- If you change your mind and withdraw the Authorization, you will not be allowed to participate in the study.

You will not be allowed to review the information collected for this research study until after the study is completed. If you are not allowed to review your information during participation in the study, when the study is over you will have the right to access the information.

This Authorization does not expire.

If you have not already received a Notice of Privacy Practices from Children's National Medical Center, you may request a copy and will be given one. If you have any questions or concerns about your privacy rights, you may contact the Children's Hospital Privacy Officer at 301-572-6348.

CONSENT/PARENTAL PERMISSION:

- I am the study participant or I am authorized to act on behalf of the participant.
- I have read this consent form or had it read to me.
- I have been invited to take part in a research study. I was told why the research is being done and what I am being asked to do.

- I was told that taking part in this research is voluntary. I also was told that I can decide not to take part or stop being in it at any time without any penalty to me or any change to the quality of care I receive at Children's National.
- I was told about the risks and possible discomforts of taking part in this research study. I was also informed if there are any possible benefits to me if I am in this study.
- I have been given the chance to ask questions about the study, and my questions have been answered. If I have questions later, I can ask one of the people listed in this form.
- I agree to take part in this research study.
- I will receive a copy of this Informed Consent/Parental Permission form to keep.

Signature of Parent(s)/Guardian for participant under the age of 18 years

Printed Name of Parent/Guardian: _____

Signature of Parent/Guardian: _____

Date and Time: _____a.m. / p.m. (circle one)

Printed Name of 2nd Parent/Guardian: _____

Signature of 2nd Parent/Guardian: _____

Date and Time: _____ a.m. / p.m. (circle one)

Signature of adult participant (18 years of age and older)

Printed Name of Participant: _____

Signature of Participant: _____

Date and Time: _____ a.m. / p.m. (circle one)

Signature of language interpreter (if applicable)

Printed Name of Interpreter: _____

Interpreter's Signature: _____

Language: _____ Date and Time: _____a.m. / p.m.(circle one)

AFFIDAVIT OF PERSON OBTAINING CONSENT / PARENTAL PERMISSION:

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 Person Obtaining Consent: _____

Research Role: _____

Signature: _____

Date and Time: _____ a.m. / p.m. (circle one)

AFFIDAVIT OF PERSON OBTAINING ASSENT FROM A 7-11 YEAR-OLD CHILD:

I have explained all aspects of the research study to the child participant to the best of his/her ability to understand.

I have answered all of the child participant's questions relating to the research study.

I believe the child participant's decision to enroll is voluntary.

The study doctors and study staff agree to respect the child participant's physical or emotional dissent at any time during this research study when that dissent pertains to anything being done solely for the purpose of the research.

Printed Name of Person Obtaining Assent: _____

Title: _____

Signature: _____

Date and Time: _____a.m. / p.m. (circle one)