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CHILDREN'S NATIONAL MEDICAL CENTER
Center of Translational Science
111 Michigan Avenue, NW
Washington, DC 20010
(201) 476-5000

Consent/Parental Permission to Participate in a Clinical Research Study and Authorization to Use Protected Health Information

STUDY TITLE:	**Childhood ADPKD Database Study**
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.

SUMMARY AND KEY INFORMTION

We are inviting you to be part of a research study at Children's National Medical Center (Children's National). **Taking part in this study is your choice.** You can choose to take part or you can choose not to take part in this study. You also can change your mind about participating at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

To help you decide if you would like to participate, we want you to know why we are doing the study, what you will be expected to do, and the possible risks and benefits of being in the study. This form has information to help you make your choice about whether or not to participate.

PURPOSE OF STUDY

Autosomal Dominant Polycystic Kidney Disease (ADPKD) is the most common genetic cause of renal failure. For several decades, ADPKD was regarded as an adult-onset disease. In the last decade, it has become more widely appreciated that the disease course begins in childhood. However, evidence-based guidelines on how to manage and approach children diagnosed with or at-risk for of ADPKD are lacking. Overall, there is insufficient data on the clinical course during childhood.

We want to get more information on Autosomal Dominant Polycystic Kidney Disease (ADPKD) and other hepato/renal fibrocystic diseases. We also want to expand our

web-based resources so anyone can learn about ADPKD or other hepato/renal fibrocystic diseases.

You are invited to be in the study because you have been diagnosed with a hepato/renal fibrocystic condition. You do not have any illnesses that would not allow you to participate in this study, such as autosomal recessive polycystic kidney disease (ARPKD) or any other major health problems that you were born with.

PROCEDURE

If you choose to be in this study, we will ask your permission to see your past, current, and future medical information. This study does not require a clinic visit to our center. If you choose to be in the study, we will ask for your medical information related to your disease. Some information that we could collect, would be clinic notes, lab results, and physician consult reports. You will be asked to sign a release of medical information form to allow the study team access to your medical information.

When we receive the information, the research study team will be able to enter your medical data into the Hepato/Renal Fibrocystic Diseases clinical database. There will be initial data entry in our database and follow up data entries lasting for the duration of this study or until you choose to not participate in the study anymore. We will remove your name or any other identifiable health information (such as name, address) from your received records before entering your medical data into the Hepato/Renal Fibrocystic Diseases clinical database.

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 ADPKD or another hepato/renal fibrocystic disease is not verified.

POTENTIAL RISKS/DISCOMFORT

This study will involve gathering information from patients, parents of minor patients, and your doctor and/or medical record review when necessary. There is no direct physical risk to you related to information gathering. Your medical information will be given a unique identifier number and your Personal Health Information will be held in the strictest confidence. Your name will only be known only to Dr. Guay-Woodford and the Research Coordinator. Your name and medical record number are on the data forms. The information your doctor supplies will be put into the database and referred to by a unique identifier number instead of your name.

This study may involve risks that are not currently foreseeable.

VOLUNTARY PARTICIPATION

If you are interested in learning more about this study, please continue reading below. The rest of this form gives you more important information you need to know about the study before you decide if you want to participate. The 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. It's important that you have as much information as you need and that all your questions are answered.

Your participation in this research 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 or if there are any important new findings so that you can decide if you still want to be in the study.

If you are an employee or a medical or graduate student in training at Children's National, your decision to participate or not participate will not affect your employment or academic standing.

POTENTIAL BENEFITS

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 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.

ALTERNATIVES TO PARTICIPATION

The alternative is to not participate.

QUESTIONS – WHO TO CALL

We want you to ask questions about any part of this study or consent form either now or at any time in the future. If you have any questions about this study, call the Principal Investigator, Lisa M. Guay- Woodford, MD, at 202-476-6439. If you believe you have been injured as a result of being in this study, you should call the Principal Investigator, Lisa M. Guay-Woodford, MD, at 202-476-6439. If you have

any questions or concerns about your rights in this research study at any time, please call the Office for the Protection of Human Subjects at (301)-565-8452, the Chief Academic Officer, or the Chair of the Institutional Review Board of the Children's National Medical Center. The last two parties may be reached at (202) 476-6439.

Will the information that I give you be shared with others? How will you protect my privacy?

Efforts will be made to limit the use and disclosure of your personal information, including research records, medical records, and Protected Health Information (PHI), to authorized members of the study team and to people who have a need to review this information. Your identifiable personal information will not be given to anyone unless we get your permission in writing, except as described in this consent form or if the law requires it. This information will also only be given for regular hospital care, payment, and hospital management activities. We will make every effort to keep your information private, but no one's privacy can be totally guaranteed.

Your medical record is confidential but, just like any medical record, there are some exceptions under state and federal law.

There are some third parties such as government agencies or other groups within Children's National that may check records that identify you without your permission. They might review the study records and your medical records to make sure we are following the law and protecting the people in the study and to make sure our results are correct. The agencies or groups who might see these records are [*include as appropriate:* the Department of Health and Human Services Office of Human Research Protections, Food and Drug Administration, National Cancer Institute, the sponsor *(specify study sponsor or the sponsor's designated representative, if applicable)*] and the Children's National Medical Center Institutional Review Board (the ethics board that reviewed and approved this research study) and the Office for the Protection of Human Subjects.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access.

The results of this research may be presented at meetings or in publications. You will not be personally identified.

Information that you are participating in this study will be entered into your electronic medical record. This information will be seen by any medical provider caring for you at Children's National and its affiliated institutions. In the uncommon event that you are treated outside of this research study by a medical provider affiliated with Children's

National, there is a possibility that the medical provider may contact the Principal Investigator regarding your participation in this research study. This could be necessary for your safety if the experimental treatment used in this study might interfere with a treatment being considered by the provider. The Principal Investigator will carefully decide on the type and amount of information he/she gives to the medical provider and will maintain your privacy and the confidentiality of the information to the extent possible.

1. If identifiers like your name, address, date of birth and phone number are removed from the data that are collected during this research, that information could be used for future research studies or given to another investigator for future research studies without your additional informed consent.

2. Your information that is collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers, name, address, date of birth and phone number are removed.

Genetic Information Nondiscrimination Act (GINA)

A 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.

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

A Federal law called “HIPAA” provides additional protections of your medical records and related health information. These protections are described below.

1. Your information (both identifiable and de-identified) may be used to help researchers create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you or to pay you or your family.

2. Your information (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, we plan to tell you and to pay you or your family.

ClinicalTrials.gov

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY

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 M.D., 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 name, address, telephone number, date of birth, Social Security number, and other details about you
- Information that relates to your health or medical condition from your medical records
- Information obtained from the study procedures outlined in this consent form, for example: things done to see if you can join the study such as physical exams, blood and urine tests, x-rays and other tests, and any other medical information we learn from you about your health history and family history
- Laboratory results obtained on specimens collected from you (blood, urine, tissue)
- Questionnaires or surveys you complete
- Interviews conducted with you by members of the research team

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 Department of Health and Human Services (DHHS) Office of Human Research Protections (OHRP)
    - The Food and Drug Administration
- Children's National Medical Center Institutional Review Board
- Children's National Medical Center Institutional Quality Assurance Program
- Other staff in the Human Research Protections Program 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:

- Doctors and staff at other places that are participating in the study.
- Laboratories and other people or organizations that look at your health information in connection with this study.
- The Sponsor of the study and people that the Sponsor may contract with for the study.
- The Contract Research Organization (an organization that helps the Sponsor run the study).
- The Data Safety Monitoring Board (a group of people who examine the medical information during the study)
- The Medical Monitor for the Study (a person who reviews medical information during the study)
- The Patient Advocate or Research Ombudsman (person who watches out for your best interest)

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. The database is maintained by Children's National Medical Center.

Please indicate your approval of any or all of the following by checking a box next to each statement and initialing your choice:

- 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 ADPKD.

  ☐ 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 must send a written letter to the Principal Investigator to inform her of your decision.

  Lisa Guay-Woodford M.D.
  Children's National Medical Center
  Center of Translational Science
  111 Michigan Avenue, N.W.
  Washington, DC 20010-2970

- 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.

2. 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 202-476-6464.

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 301-565-8447.

Children's National has a research participant and family advocate. The advocate is here to answer your questions or concerns about taking part in this research. The advocate does not work for the doctors who are doing this research and is not paid by the researchers. The advocate is here only to help and protect you during any research.

You may contact the research advocate 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 contact the research advocate at 202-476-5586 or by email at RSA@childrensnational.org. In urgent situations the research advocate and pediatric ethics program team can be reached at the pager number: 202-259-2082.

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 how long my participation in the study is expected to last. I was told about what will happen in the study and if there are any procedures or drugs that are experimental.
- 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 signed copy of this Informed Consent/Parental Permission form to keep.

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

Printed Name of Participant: _____

Printed Name of Parent/Guardian:_____

Signature of 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, possible risks, and potential benefits 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: _____

Research Role: _____

Signature: _____

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

Signature of Witness to Consent Process (if applicable)

Printed Name of Witness: _____

Witness's Signature: _____

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