Children's Hospital of Philadelphia

Informed Consent and HIPAA Authorization Form

Study Title: **Autosomal Dominant Polycystic Kidney Diseases (ADPKD) Database study**

Principal Investigator: Lisa Guay-Woodford, M.D. Telephone: 267-425-0315

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You, or your child, may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

In the sections that follow, the word "we" means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word "you" refers to your child.

Study Overview

You are being asked to take part in this research study because you have autosomal dominant polycystic kidney disease (ADPKD).

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.

The purpose of this study is to get more information about ADPKD.

If you agree to take part, your participation will last for around one hour. It will involve one study visit and an annual follow-up till the end of the study or until you choose to end participation. As a participant in the research you will asked to participate in

- Medical history review
- Optional urine sample
- Optional blood sample

Data and/or samples collected will be used to create a database that may help us to better understand this rare condition. We also hope to create resources that could be used by families, and their physicians. There are risks to all procedures; including risk of breach of confidentiality and minimal risks to the optional sample collection.

You will not benefit directly from participating in this study.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

Please see below for additional details about the study.

How many people will take part?

About 500 people will take part in the study, including approximately 100 participants from Children's Hospital of Philadelphia (CHOP).

What are the study procedures?

Tests that are part of your regular, routine medical care will continue to be performed. The study involves the following tests and procedures.

Medical history review: Information (data) will be collected from your medical records and from a brief interview. The information will include your diagnosis, treatments, and medications. If you are cared for at CHOP, your data will be updated every year until you turn 18 years of age as long as the study is on-going. If you are still cared for at CHOP after you turn 18, we will request that you continue to allow us to update your information. 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.

Alternative optional urine sample: If you are interested in participating in the optional urine sample collection, you will agree to give aurine sample to this research study at your clinical visit. We will do our best to collect the samples at the same time as a clinic urine collection. The urine will be collected as a research sample with will be a clean catach sample using a cup.

Alternative optional blood sample: If you are interested in participating in the optional blood sample collection, you will agree to give a blood sample to this research study at your clinical visit. We will do our best to collect the samples at the same time as a clinic blood test. We will try not to stick you more than once.

What will be done with my data and specimens during this study?

Research study team will be enter your coded medical data into the ADPKD clinical database.

Samples (if you choose to do optional sample testing) will be processed and stored at CHOP for research purposes.

Will I receive any results from the tests done as part of this study?

Testing done for this study will be done for research-puposes only and may not have valuable health care use. If we think that there are research results that will be beneficial for you, we will contact you and/or your clinician.

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. The main risks of taking part in this study are discussed below.

Risks of blood tests:

Taking blood may cause some pain, bleeding or bruising at the spot where the needle enters your body. Rarely, taking blood may cause fainting or infection. \. If you choose to do the research blood draw at CHOP, it can be combined with clinical blood draws to minimize risk.

Risks of urine sample:

There are no physical risks but you might experience momentary embarrassment.

Risks of Medical Record Review and Breach of Confidentiality:

As with any study involving collection of data, there is the possibility of breach of confidentiality of data. Every precaution will be taken to secure participants' personal information to ensure confidentiality.

At the time of participation, each participant will be assigned a study identification number. This number will be used on data collection forms, blood samples, urine specimens and in the database instead of names and other private information. A separate list will be maintained that will links each participant's name to the study identification number for future reference and communication.

Are there any benefits to taking part in this study?

There are no direct benefits to you from participating in this study. An indirect benefit would be that results from this research may provide important insight for the future care of people with these conditions.

Do you need to give your consent in order to participate?

If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. Your health care provider at CHOP will continue to provide you with health care services even if you refuse to sign this form.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

Can the study doctor take you out of the study early?

The study doctor may take you off of the study if:

- Your condition worsens.
- The study is stopped.
- You cannot meet all the requirements of the study.

- New information suggests taking part in the study may not be in your best interests.

What choices do you have other than this study?

There are options for you other than this study including:

- Not participating in this study.
- You may discuss other options available to you with your doctor.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you will be collected. This will include information from medical records, interviews, and sample tests (if applicable). Medical records are available to CHOP staff. Staff will view your records only when required as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone – unless you provide your written consent, or it is required or allowed by law. Sample test results (if applicable) will not appear in your medical records. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP.
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.
- The National Institutes of Health who is sponsoring this research;
- If you agree, your data will be shared through databases that may be publicly available to anyone. The data will not include identifiers like your name, medical record number or date of birth. To use your data, researchers must promise not to try to re-identify you. You can tell us at the end of this form whether you will allow is to share your data in this way;

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

The identifiable information from this study will be destroyed six years after the study is completed.

Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. Lisa Guay-Woodford
The Children's Hospital of Philadelphia
Division of Nephrology
34th Street and Civic Center Blvd.
Philadelphia, PA 19104

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Certificate of Confidentiality (CoC)

A Certificate of Confidentiality (CoC) issued by the NIH covers this research. A CoC helps protect your identifiable information and biological samples.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

- No one can be forced to share your identifiable information or biological samples for a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

If you consent, your information or biological samples could be shared for:

- other scientific research;
- your medical treatment

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The NIH may need information to assess this project.
- You can still share information about yourself. You can also freely discuss your involvement in this research.

- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance.

Will there be any additional costs?

There will be no additional costs to you by taking part in this study.

CHOP is providing financial support and material for all optional sample testing procedures, as listed above, for this study.

Will you be paid for taking part in this study?

You will not receive any payments for taking part in this study.

Who is funding this research study?

The National Institutes of Health is providing funding for this study.

Please ask Dr. Lisa Guay-Woodford if you have any questions about how this study is funded.

What if you have questions about the study?

If you have questions about this study or how your samples/data are going to be used, call the study doctor, Dr. Lisa Guay-Woodford at (267) -425-0315. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

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.

Sharing Data with the National Institutes of Health (NIH)

Why will my data be shared with the National Institutes of Health (NIH)?

The NIH is funding this study. The NIH's goal is to maximize the benefits that come from the research.

The NIH repository stores information and phenotypic data from many studies. The NIH then shares that information with researchers. We will send the information about you and the other participants to a repository at the NIH. The information will be de-identified (no names or other direct information about you will be included). The NIH will not be able to re-identify you or any other individual.

The NIH intends to share the collected information with other researchers for future research. The researchers who receive data must promise to keep the data confidential

and to use it only for the purpose approved by NIH. They must also promise to not try to re-identify anyone.

Risks Associated with Sharing Data with the NIH

There are risks associated with sharing your data with the NIH but they are very unlikely to occur. There is only a very small chance that someone could find out that the data came from you. If that happened, it's possible that someone could deny you a job or health insurance. Or you could experience stress, anxiety, or embarrassment.

Benefits Associated with Sharing Data with the NIH

Sharing your information for future research will not directly benefit you. It is hoped that it will lead to a greater understanding of the interaction between genes and health. This knowledge could help others in the future.

Controlled or Unrestricted Access

The data about you will either be made available by the NIH through controlled access or unrestricted. Controlled access means the data are made available for other research only after investigators have obtained approval from NIH to use the requested data for a particular project. Data for unrestricted access are publicly available to anyone (e.g., The 1000 Genomes Project).

OPTIONAL CONSENT for collection of blood sample for testing

If you wish to consent to blood testing, please select only ONE option

_____ (initials) I agree to have **blood** taken for research sample testing.

_____ (initials) I do not wish to take part in blood sample testing for this research.

OPTIONAL CONSENT for collection of urine sample for testing

If you wish to consent to urine testing, please select only ONE option

_____ (initials) I agree to have **urine** taken for research sample testing.

_____ (initials) I do not wish to take part in urine sample testing for this research.

What will be done with my data and/ or specimen when this study is over?

By agreeing to participate in the study, your de-identified medical information and blood sample (if collected for optional testing) will be used to :

- Expand our eatablished clinical database that includes information from all patients who meet the inclusion criteria for ADPKD.
- (if you choose to do optional testing) Develop a mutational database that may help futher research in ADPKD.

- Expand our multi-media, web-based resource for families and their physicians affected by these conditions.

Separate optional consent will be taken below if participants wish to be contacted for future research, by maintaining their contact information after the study is over.

OPTIONAL CONSENT for Use of Identifiable Data or Specimens for Future Research

As part of the study, we will collect:

- 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)

We may wish to use and share this information or samples in a future study about ADPKD.

Research could occur at CHOP, or at outside institutions, which could include for profit companies. The information and samples will be given a unique code. A master list with identifiable information that can be linked back to the uniquely coded data or samples, will only be accessed by research staff and can be used to contact you for future research with your consent. This master list will be maintained by authorized research staff at CHOP only.

You will not receive any results or financial benefit from the future research done on your specimens or data.

If you leave the study, you can ask to have the data collected about you removed or the samples destroyed. You can also ask us to remove information that identifies you from the data or samples. This may not be possible if your samples and data have already been shared.

Please indicate whether you will allow the identifiable data or samples to be used for future research by putting your initials next to one of the following choices:

_____ (initials) NO, my identifiable (data and/or blood/urine specimen, as applicable with consent) may not be used for future research. They may be used for this study only.

_____ (initials) YES, my identifiable (data and/or blood/urine specimen, as applicable with consent) may be used for other future research studies.

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to your child's participation. You are also authorizing the use of your/your child's health information as discussed above. If you don't agree to the collection, use and sharing of health information, you cannot participate in this study.

Name of Subject	
Signature of Subject (18 years or older)	Date

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

By signing this form, you are indicating that you have had your questions answered, you agree to take part and to allow your child to take part in this research study, and you are legally authorized to consent to your child's participation. You are also agreeing to let CHOP use and share the health information that will be collected for this study, as explained above. If you don't agree to the collection, use, and sharing of health information, you and your child cannot participate in this study.

NOTE: *A foster parent is not legally authorized to consent for a foster child's participation.*

Consent for Child's Participation

Name of Subject	
Name of Authorized Representative	Relation to subject: ☐ Parent ☐ Legal Guardian
Signature of Authorized Representative	Date

Child Assent to Take Part in this Research Study

For children capable of providing assent:

I have explained this study and the procedures involved to _____ in terms he/she could understand and that he/she freely assented to take part in this study.

Person Obtaining Assent	
Signature of Person Obtaining Assent	Date

This study has been explained to me and I agree to take part.

Signature of Subject (optional)	Date

For children unable to assent:

I certify that _____ was not capable of understanding the procedures involved in the study sufficiently to assent to study participation.

Person Responsible for Obtaining Assent	
Signature of Person Responsible	Date

STUDY SUMMARY SIGNATURE PAGES

For Subjects with Limited English Proficiency

Consent to Take Part in this Research Study and Authorization to Disclose Health Information

Name of Subject

Name of Authorized Representative
(if different than subject)

Relation to subject:
☐ Parent ☐ Legal Guardian

The research study and consent form have been explained to the subject or parent/legal guardian.

By signing this form, you are indicating that you have answered the subject's or parent's/legal guardian's questions, they have agreed to take part in this research study and they are legally authorized to consent to their or their child's participation. They have also agreed to let CHOP use and share their or their child's health information as explained above. If they don't agree to the collection, use and sharing of their or their child's health information, they cannot participate in this study.

Person Obtaining Consent

Signature of Person Obtaining Consent

Date:

Witness/Interpreter

By signing this form, you are indicating that

- The information in the Summary Document as well as any additional information conveyed by the person obtaining consent was presented to the subject in a language preferred by and understandable to the subject; and
- The subject's questions were interpreted and the responses of the person obtaining consent were presented in a language preferred by and understandable to the subject.
- At the conclusion of the consent conference, the subject was asked in a language preferred by and understandable to the subject if s/he understood the information in the Summary Document as well as any additional information conveyed by the person obtaining consent (including responses to the subject's questions) and responded affirmatively.

Name of Witness/Interpreter

Signature of Witness/Interpreter

Date:

Child Assent to Take Part in this Research Study

For Subjects with Limited English Proficiency

For children capable of providing assent:

I have explained this study and the procedures involved to _____ in terms he/she could understand and that he/she freely assented to take part in this study.

_____
Person Obtaining Assent

_____ _____
Signature of Person Obtaining Assent Date

Witness/Interpreter

By signing this form, you are indicating that

- The information in the Summary Document as well as any additional information conveyed by the person obtaining assent was presented to the subject in a language preferred by and understandable to the subject; and
- The subject's questions were interpreted and the responses of the person obtaining assent were presented in a language preferred by and understandable to the subject.
- At the conclusion of the consent conference, the subject was asked in a language preferred by and understandable to the subject if s/he understood the information in the Summary Document as well as any additional information conveyed by the person obtaining assent (including responses to the subject's questions) and responded affirmatively.

_____ _____
Name of Witness/Interpreter Signature of Witness/Interpreter

Date: _____