

# Consent form

## *Information about the ADPKD Patient Registry*

You are being asked to be in a research Registry run by the PKD Foundation. The PKD Foundation is the only organization in the U.S. solely dedicated to finding treatments and a cure for PKD to improve the lives of those it affects. Our vision is to #endPKD.

Before you agree to take part in the ADPKD Patient Registry, it is important that you understand what is involved, what information you may receive, and what will be done with the information you provide. Please read this form carefully. The Registry staff can provide answers about the ADPKD Patient Registry provide link to FAQs and contact information.

If you are the parent or legal guardian of a child who may take part in this Registry, your permission and the permission of your child will be needed. When “you” appears in this form, if applicable it may refer to you or your child.

For questions about the Registry Goals and details of the ADPKD Patient Registry, contact the Registry Lead at [registry@pkdcure.org](mailto:registry@pkdcure.org). For all other questions, please visit the [PKD Foundation website](#) or the [PKD Connect](#) webpage, or call the PKD Hope Line at 844.PKD.HOPE (844.753.4673). You should also discuss this Registry with anyone you choose in order to better understand this Registry and your options.

A copy of the information in this form will be available to you via your website account. Additional information about this Registry is available in the ADPKD Patient Registry FAQ.

## *What is the ADPKD Patient Registry?*

A patient registry is a database that collects health information of people with a specific disease or condition. In addition, a Registry keeps information in one place making it easier for researchers to utilize medical information while still protecting the privacy of those who take part. The ADPKD Patient Registry will collect data most relevant to your ADPKD diagnosis, its major symptoms and management, as well as key demographic data (no personally identifiable information is shared without your permission).

## *Purpose and Goals of the PKD registry:*

The purpose of the ADPKD Patient Registry is to support important scientific discoveries and support patient needs by pursuing these Registry Goals:

- **Research:** Supporting research to find treatments and a cure for PKD. For example, “de-identified” information about how the ADPKD disease affects a large number of patients can be very helpful for scientists in their research efforts. Data provided by patients will inform new research to improve ADPKD patient outcomes, learn more about the patient journey and discover unmet medical needs.

- **Development:** Supporting the development of new medications and treatments for the ADPKD disease. For example, the ADPKD Patient Registry can connect ADPKD patients with opportunities to join clinical studies of new medications and treatments.
- **Measuring Outcomes:** Engaging with patients by measuring quality of life outcomes and collecting information to better describe the ADPKD disease experience. For example, confidential health-related surveys will provide better understanding of the health of people with PKD across their lifespans.

### *Who is paying for this Registry?*

The ADPKD Registry is fully funded by the PKD Foundation so there is no charge for participation. Support for the PKD Foundation may come from charitable gifts by individual donors, other foundations, corporations, pharmaceutical companies or other collaborators.

### *Will being in this Registry help me?*

You will not benefit directly from participating in the ADPKD Patient Registry. You may receive information that you find helpful, such as information about PKD research and other ADPKD Patient Registry Goals (see above). The information collected by the ADPKD Patient Registry may help researchers gain a better understanding of PKD and may lead to better diagnostic tests and treatments. By taking surveys you may learn about ADPKD Patient Registry research findings, including how your answers compare with those of other PKD patients and new discoveries made by ADPKD research programs.

### *Will it cost anything to be in this Registry?*

There is no cost for you to join the Registry. This is not a treatment study.

### *How long will I be in the Registry?*

If you decide to join this Registry, your participation will last as long as the Registry is active or until you decide to withdraw from the Registry. If you do withdraw, the Registry cannot retract the use of de-identified data from surveys prior to the date you decided to withdraw and cannot remove your de-identified data from the Registry.

### *What will happen during my time in the Registry?*

While you are in the Registry, you are expected to:

- Provide initial demographic information, such as your name, date of birth, gender, date of diagnosis, location of residence and other similar information.
- You will enter information about yourself such as diagnosis, lab results, current symptoms and medications into the ADPKD Patient Registry website.
- You will also be asked every so often to complete online surveys of varying lengths. Each survey will take approximately 5–20 minutes to complete. Filling out surveys is optional and voluntary.
- Family members with PKD are welcome to join the Registry. You will be asked to identify your relationship with other family members with PKD, but you will not need to provide their names.

- The ADPKD Registry is open-ended: new surveys may be added on a continuing basis. If new surveys are added, we may invite you to complete these activities or invite you to join a specific study if your responses match the area of interest. Such invitations will be sent using routine communication methods, such as email, push notifications or announcements when you sign in to your account.
- You may be asked to provide details of your time in other research studies, and your study doctor may update the Registry database with information obtained from your study records.
- Your family members or a caregiver may provide updates if you are not available.

Reminders will be sent to participants via email and website/app notifications when surveys or other tasks are due or missing. ADPKD Patient Registry staff will contact participants with reminders for assessments available assessments not yet completed.

Giving consent below means that you agree to let the ADPKD Patient Registry provide information to you and use the information that you provide to the Registry for the Registry Goals.

- *Providing information to you:* The PKD Foundation may use the Registry to provide information to you for the purposes generally described in the Registry Goals. You do not need to read the information, take any actions, or provide any response to the information. How you use the information is your choice.
- *Using information that you provide:* You do not have to enter information you do not feel comfortable sharing and you may choose to complete all, some, or none of the surveys.

Participants will be provided the option to take part and opt-in to future studies conducted by the PKD Foundation, ADPKD Patient Registry and its partners. Any information that you share with anyone outside of the ADPKD Patient Registry is your choice and not covered by the steps the ADPKD Patient Registry takes to de-identify information.

If available in the future, the Registry may choose to use and share de-identified information with other parties, such as the National Institute of Health (NIH), pharmaceutical companies, academic institutions or individual researchers, which may help to expand research on PKD. In the event of any publication or presentation resulting from the Registry, no personally identifiable information will be shared. No one other than the PKD Foundation will be able to contact you directly regarding taking part in research.

### *Do I need to come in for study visits?*

No, this is not a treatment study. You will be asked questions about your treatment, but no in-person visit is necessary. All information will be collected via phone interviews, email, questionnaires or internet updates.

### *Are there risks to me if I am in this Registry?*

There are no health risks associated with joining this Registry. Although we will take every precaution to protect your personal information, there is a risk that your privacy may be compromised. In the unlikely situation where this happens, you will be notified right away. Keeping the information from your survey in a secure computer database will limit that risk, but does not eliminate it. ADPKD Patient Registry staff are trained on how to work with human research participants. If you share your login and password with others, they may be able to access your account and self-reported survey answers. There may be other risks that are currently unknown.

If you change your mind and no longer want to be part of the ADPKD Patient Registry, you may contact the ADPKD Patient Registry Coordinator by e-mail at [registry@pkdcure.org](mailto:registry@pkdcure.org). Your account will be deleted; however, the ADPKD Patient Registry cannot retract the use of de-identified data from surveys prior to the date you decided to opt-out. In the event this Registry is terminated, the PKD Foundation will maintain your participant data according to the terms of our Privacy Statement.

You may decide to not join or you may leave the Registry at any time.

### *Will I receive payment?*

No; you will not receive any payment for being in the Registry.

### *Do I have to be in this Registry?*

Your participation in the Registry is voluntary. The care you receive from your regular doctor will not be affected in any way, whether or not you decide to be in the Registry. If you want to stop being in the Registry, tell the PKD Foundation at [registry@pkdcure.org](mailto:registry@pkdcure.org). If you decide to withdraw from the Registry, the PKD Foundation may ask you some questions about being in the Registry. You can still take part in other PKD Foundation activities even if you choose to leave this Registry. Deciding not participate or withdrawing will not result in any penalty or loss of benefits to which you are otherwise entitled.

### *What if I work with the PKD Foundation? What if I am a family member of someone who works with the PKD Foundation?*

#### *For adults considering whether to be in the Registry:*

PKD Foundation employees and their family members do not have to be in this Registry. No one should influence or pressure you to be in this Registry. An employee's or his/her family member's decision to be in the Registry, or to leave the Registry early, will not affect the employee's job or job benefits.

#### *For parents/guardians who are considering whether to allow their child to be in the Registry:*

PKD Foundation employees and their family members do not have enroll their children in this Registry. No one should influence or pressure you to let your child be in this Registry. An employee's or his/her family member's decision to allow a child to be in this Registry, or to have the child leave the Registry early, will not affect the employee's job or job benefits.

### *Who can I talk to about this Registry?*

In the event of an emergency, dial 911 immediately. Do not contact the PKD Foundation with emergency situations. Registry updates of your medical condition can wait.

You can ask questions about the Registry at any time. You can call the PKD Foundation's PKD Hope Line at 844.PKD.HOPE (844.753.4673) at any time if you have any questions, concerns or complaints or think you have been harmed by the research. The Registry staff cannot answer questions about the reasons or validity of your medical treatment. This type of question should be referred to your regular doctor(s).

The New England IRB reviewed this Registry. The New England IRB is a group of people who review research studies to protect the rights and welfare of research participants. If you have questions about your rights as a research participant, if you are not able to resolve your concerns with the Registry staff, if you have a concern or complaint, or if you have general questions about what it means to be in a research Registry, you can call 800.232.9570 or visit [www.neirb.com](http://www.neirb.com).

## Who will use and share information about my being in this Registry?

During your time in the Registry, the Registry staff will use, collect, and share health information about you (your “records”). Your records may include any information about you that you provide, such as your name, address, phone number, and medical information. The Registry aims to share detailed medical and other information for the Registry Goals, while still protecting your privacy. This is done by hiding the name, address and other “identifying” information from the researchers and others. We call this information “de-identified” because it has been removed of all personal identifiers. Your personal information will be stored in a secure place and protected with a password. Only authorized people who work in the Registry will be able to identify you if needed.

If a researcher wants to access your name or other identifying information, the Registry staff will ask your permission first. Otherwise, your name and identifying information will only be used or shared when required by law. Your records may be used and shared with these people in the following situations:

- The New England IRB can also access the information in the Registry.
- You release your information to other people not involved in the Registry.
- You agree in writing to the release of your information to other people.
- The Registry staff suspects things they must report under federal, state, or local law, including child or elder abuse, certain communicable diseases, or a possible threat to you or others. There may be other things the Registry staff must report under law.

The PKD Foundation or Registry staff may use some facts about your data in this Registry in books, magazines, journals, and scientific meetings. The Registry staff may also use or share Registry data to generate revenue for the PKD Foundation. If this happens, only de-identified data will be used (that is, without your name, contact information or other personally-identifying information).

[You have the right to see and copy your records related to this research. You can cancel this authorization and leave the Registry at any time. You will be able to view a copy of this form in your participant portal.](#)

- I understand the purpose and nature of the ADPKD Patient Registry, and I have no additional questions.
- I give permission for the information I share in the Registry to be used for the Registry Goals and provided to researchers, other registries or databases. The information will be shared anonymously unless I give express permission for identifying information to be shared.
- My participation in the Registry is entirely my choice. If I change my mind and wish to withdraw my participation, I will be free to do so at any time without having to provide any explanation, and I will not be penalized in any way for withdrawing my consent.
- I understand the risks and benefits of participation and I agree to participate in the ADPKD Patient Registry.

[If you are registering a child under 18 years of age:](#)

- The child I am registering has given me his/her assent (agreement) to include his/her information in the ADPKD Patient Registry; OR the child I am registering is not able to understand the idea of participating in a Registry and I am making the choice for him/her.