Patient information and informed consent to the participation in the ARPKD registry study ARegPKD

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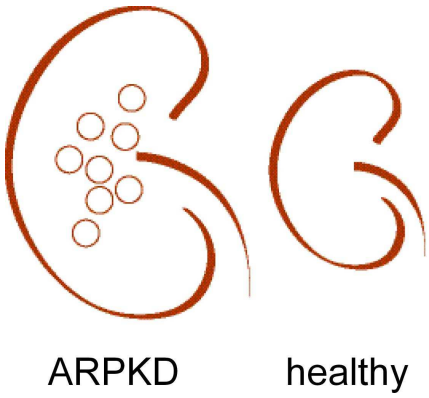
Dear patient,

Your doctor has told you that you have "autosomal recessive polycystic kidney disease" (ARPKD) and has asked you to participate in our ARPKD patient registry study. With this form we want to give you information on why we undertake this registry and what participating would mean for you. Please take some time to read the following information carefully and please consult your doctor if you have any further questions.

What is known about ARPKD?



ARPKD is an inborn disease that mainly affects the kidneys and the liver. It makes your kidneys too big while at the same time making them work less well than in other children. ARPKD may present with different symptoms.

Scientists all over the world have learned a lot about how kidneys become cystic. Nonetheless, there currently is no causative treatment of ARPKD and we do not yet understand why some children become more ill than others.

It is therefore very important for us to learn as much as possible about this disease.

What are the goals of the ARPKD registry? Why is ARegPKD being conducted?
ARegPKD will aim (?) to collect the stories of ARPKD patients from different countries all over the world (mainly across Europe). How have patients been treated in different countries so far, and which treatments did show good results? We also want to look for the inborn information that leads to a milder or more severe course of ARPKD.

As ARPKD is a rare disease each doctor has only a few patients with this disorder. We therefore want to collect the data from other centers and countries in a central registry. For that reason, the registry is being supported e.g. by the German Pediatric Nephrology Association (GPN).

Who can take part in the registry? How to register?

Only doctors can submit data to ARegPKD. You do not have to introduce data yourself. Any ARPKD patient can participate in ARegPKD.
However, your doctor can only include the data once you allow him to do so.

Who cannot take part in the registry?
Patients with a different cystic kidney disease to ARPKD may not participate.

How is ARegPKD being conducted? Which data are collected? Which examinations will be performed?
If you and your parents agree, your doctor can enter information on your story into a data base.

Your name and address will not be saved. Your name will be replaced by an ID-code (e.g. Harry Potter in Cologne → 01-13). Only your doctor will be able to link this ID data back to you. Every year your doctor will enter information on how you are.

Information on the handling of biological samples. How will biological samples be obtained? What will happen to these samples?
When a blood sample is taken during a routine visit, we will take an additional blood sample on the same occasion. The amount of blood required for these analyses will be 5 to 30 ml. We will take 2-10 ml of blood once every year. This process will then be repeated when blood is taken anyway.

From your bloodanalyses e.g. on your genetic material can be performed. These will be done by our partners. These are currently Prof. Dr. C. Bergmann at the Bioscientia Institut für Medizinische Diagnostik GmbH, Labor Ingelheim mit Zentrum für Humangenetik in Ingelheim, Germany and Prof. Dr. K. Zerres at the University Hospital Aachen, Institut für Humangenetik in Aachen, Germany.

If you get a biopsy, we want to collect a small piece of the biopsy and store it for further analyses and for further research on the disease.
ARegPKD offers biopsy material being microscopically analyzed by someone who knows a lot about ARPKD. This will be done by Prof. Dr. R. Büttner at the Institute of Pathology of the University Hospital of Cologne.

We want to collect blood samples and other samples from our patients and store them in a so-called “biobank”. From these samples e.g. genetic material can be isolated, which shall also be stored.

If you agree the samples will only be used for scientific research on cystic kidney diseases.

Will there be additional examinations or additional consultations required for ARegPKD?
No. Your doctor will introduce the data into the registry. There will be no additional examinations or hospital visits that would not be performed otherwise. Moreover, there will be no additional takings of blood samples.

Which risks result from ARegPKD?

ARegPKD is a registry study. Within ARegPKD existing data will be collected. You will not be treated differently. During the blood takings of routine visits that your doctor would collect anyway, an additional small blood sample will be taken for ARegPKD.

How do you or your doctor profit from the participation? Are there any costs? Will you get any gratification?
There are no direct advantages for you. Potentially all ARPKD patients may profit from the results obtained within this registry study. There will be no costs. Nor will there be any gratification.

What happens to my data?
All data and findings will be treated confidentially, no one of us may talk about this to anyone. At the end of the study we write an article about the results, but in such a way that no particular patient can be identified from it, including yourself.

Do I have to participate?
No. The participation in the study is completely voluntary. You can, at any time, and without telling us why, withdraw your participation. There will be no disadvantage for you. You will not be treated differently. But we would be happy if you did participate.

Who is your contact person?
Your first contact person for his study is your corresponding doctor.

Local doctor:
Name:
_____
Institution:
_____
Phone:
_____

Futher questions?
Please do not hesitate to contact us for further questions you may have.

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Participation in ARegPKD

Consent

_____ _____
(patient name)

Please read the following sentences and statements carefully. Take your time for your decision. Please mark **"Yes"** or **"No"**. Your medical treatment will not be influenced by your decision in any way.

Have you read the explanations on this research (or has someone read it to you)?	□ Yes	□ No
Has someone explained the analyses to you?	□ Yes	□ No
Do you understand what this research is about?	□ Yes	□ No
Have you asked everything you wanted to ask?	□ Yes	□ No
Have you understood the answers to your questions?	□ Yes	□ No
Have you understood that you can quit the study at any time and that this is ok?	□ Yes	□ No
Do you agree to participate in this study?	□ Yes	□ No

If you answered any of the above questions or statements with „No" or if you do not want to participate, please do not sign this form!

_____, _____ Patient: _____
(place) *(date)*

Name of informing doctor: _____

_____, _____ Doctor: _____
(place) *(date)*