Title of the study: **ADPedKD: An international web-based database for longitudinal data registry of children with Autosomal Dominant Polycystic Kidney Disease (ADPKD)**	
Sponsor of the study:	**UZ Leuven**
Research Institution:	**UZ Leuven, Herestraat 49, 300 Leuven**
Medical Ethics Committee:	**Ethische Commissie onderzoek UZ / KU Leuven**
Local investigators:	**Prof. Dr. Djalila Mekahli** (Djalila.mekahli@uzleuven.be)
Clinical trial assistant:	**Lotte Vanmeerbeek** (lotte.vanmeerbeek@uzleuven.be)
Department of pediatric nephrology: U.Z. Leuven | Herestraat 49 - 3000 Leuven | Tel (016) 34 38 22	

Dear ..... ,

You are being followed up by your doctor because you have "Autosomal dominant polycystic kidney disease (ADPKD)." Therefore, you are now being asked to participate in the ADPKD patient registry, which is called ADPedKD. It is important that you understand why this study is being conducted and exactly what we want to do before you decide whether to participate. Please read this information carefully. There may be some difficult words in this letter that you do not understand. You can ask the doctor/researcher at any time to explain these words, or to go over the information with you. If after reading this letter you decide to participate in the study, we will ask you to fill in your name and sign it. This is how you indicate your agreement. Your father, mother, or legal guardian will also sign a similar letter. If you prefer not to participate, you may tell the doctor. You do not need to give a reason for this.

What is ADPKD?

"Autosomal Dominant Polycystic Kidney Disease" (abbreviated as ADPKD) is common: in one in 400 to one in 1000 people. The disease is caused by a genetic flaw. As a result, cysts grow in the kidneys, which, as people age, can work less well. At the moment, there is no drug that can stop this; this is known from studies on adults with the disease. There is still a lot we do not know about the disease. We cannot predict how quickly the kidneys will become inactive in patients with this disease. Sometimes we can see signs of the disease in children, such as more protein in the urine than normal or the presence of higher blood pressure. You will come for a check-up every year like other children with 'ADPKD', or sooner if we feel it is necessary. Sometimes we give children medication for high blood pressure or the increased protein in the urine, in order to protect the kidneys as best as possible.

Why do we do this study?

ADPedKD aims to collect data on ADPKD patients from childhood or even before birth all over the world. How have patients been followed up and treated so far in the different countries and which treatments gave a positive result? We also want more information on what leads to a milder or worse (from a younger age) course of ADPKD. Particular attention will be given to the initial presentation of the disease, birth data, genetic testing and follow-up.

What does participation in the study involve?

If you and your parents agree, the medical staff can add your information (symptoms, radiological tests, laboratory results, family history, genetic research results and so on) to the database.
Your name will be replaced by a code. Only the principal investigator or an authorized member of the research team will be able to link your data to your name. This person will add new information on your succession to the database every year.

Will additional tests or additional consultations be required for ADPedKD?

No. The medical staff will enter your information into the registry. There is no additional examination or hospital consultations required that would not otherwise be necessary.

What are the advantages and disadvantages of this study for you ?

There are no additional risks associated with participating in this study since we are only collecting existing data in ADPedKD. You will not be treated differently by your doctor.
Participating in this study has no immediate benefits for you, but it may allow us to better help people with ADPKD in the future.

What happens to the results of the study?

We treat all results with the utmost privacy in accordance with the European General Data Protection Regulation (AVG) and Belgian Law on the Protection of Natural Persons with regard to the Processing of Personal Data. All researchers will work with encrypted data so that your data can never be directly linked to your name. This means that your identity will be replaced by an identification code in the study. The link between your identity and the code for the study will be stored on the secure servers of UZ Leuven and can only be accessed by the research team. Only coded data will be analyzed and the analyses will be performed electronically and under the supervision of the researchers. More information on this can be found in the appendix of this consent form.
A participation in this study is completely free and voluntary and can be terminated by you at any time.
This study has been approved by the Research Ethics Committee UZ/KU Leuven and is insured according to the provisions of art. 29 of the Belgian law of 7/5/2004. The results obtained may be published.

What happens if you do not want to participate in this study?

Participation in this study is voluntary, it is your choice. You may refuse to participate in this study, or let it be known at any time that you no longer wish to do so. Even if you have already participated, you may still decide not to continue with the study. This will not change how we will care for you.

Who will conduct this study?

This study will be conducted by Prof. Dr. Djalila Mekahli. If you have any questions regarding the study, you can contact the secretariat of pediatric nephrology (016/34.38.22) or a member of her study team (Vanmeerbeek Lotte).
If you have any questions regarding your rights as a participant in the study, you can contact the ombuds service in your hospital at the telephone number: +32 16 34 48 18. If necessary, the ombudsman service can put you in contact with the Ethics Committee.
If you want to participate, you can put your name and/or signature on the next page. This is not an obligation, but a statement that you understand and agree with everything that has been explained herein.

Name of the child: _____

Signature of the child: _____ Date: _____

Name of the parent:_____

Signature of the parent: _____ Date:

Undersigned, the investigator, clinical research assistant, or I confirm that I have verbally provided the necessary information about the study and have given the participant a copy of the information document.

I confirm that no pressure was applied to persuade the patient to agree to take part in the study and that I am willing to answer any additional questions if required.

I confirm that I operate in accordance with the ethical principles set out in the latest version of the "Helsinki Declaration", the "Good Clinical Practices" and the Belgian Law of 7 May 2004 related to experiments on humans.

_____
Name of the investigator

_____ _____
Signature of the investigator Place and date

NOTE: As soon as the age of 18 years is reached during the course of the study, the document "Patient information and informed consent for adult" must be signed.

Appendix: Supplementary information on the protection and rights of the participant in a clinical study

Ethics Committee

This study has been reviewed by an independent Ethics Committee, namely the Ethics Committee of Ethische Commissie Onderzoek UZ/KU Leuven, which has issued a favorable opinion. It is the task of the Ethics Committees to protect people who take part in a clinical trial. They make sure that your rights as a patient and as a participant in a clinical study are respected, that based on current knowledge, the study is scientifically relevant and ethical.

The Ethics Committees shall issue an opinion on these matters in accordance with Belgian law of May 7, 2004.

You should not under any circumstances take the favorable opinion of the Ethics Committee as an incentive to take part in this study.

Voluntary participation

Do not hesitate to ask any questions you find helpful before you sign. Take the time to talk about it with a confidant, if you would like to.

Participation in this study is voluntary; it is your choice. You may refuse to participate in this study, or let it be known at any time that you no longer wish to do so, without having to give a reason. Even if you have already participated, you may still decide not to continue with the study. The data we have collected so far will be used for the analyses. If you decide to stop the study, this will not change your relationship with doctor-investigator or how we will care for you.

Costs associated with your participation.

You will not be compensated for your participation in this study. However, your participation will also not result in any additional costs to you.

Confidentiality Guarantee

We treat all results with the utmost privacy. UZ Leuven is the controller of the processing of your data.

You have the right at all times to ask the researcher which data are being collected about you and what the purpose of this is. The data concern your current clinical situation, but also your medical history and the results of examinations carried out to treat your health. You also have the right to inspect the data and have any necessary corrections made if they are wrong.

The medical examiner is obliged to keep the data collected confidential. This means that he will never reveal your name in a publication or conference and will code your data (your identity will be replaced by an identification code in the study) before processing them. The link between your identity and the code for the study will be kept on the secure servers of UZ Leuven. The doctor-researcher and his team will be the only persons who can establish a link between the transferred data and your medical file[1].

The personal data transferred do not include any combination of elements that would make it possible to identify you[2].

Only encrypted data will be analyzed and the analyses will be carried out electronically and under the supervision of the researchers.

[1] For clinical studies, the law requires that this link to your file be kept for 20 years.
[2] Therefore, the database containing the results of the study will not contain items such as your initials, gender, and full date of birth (dd/mm/yyyy).

In order to check that the study is carried out correctly, persons bound to it may consult your medical file. This can only happen under strict conditions, under the responsibility of the physician-investigator and under his/her supervision (or one of his/her research assistants).

The (coded) research data may be passed on to Belgian or other regulatory authorities, to ethics committees, to other physicians and/or institutions working with the sponsor.

Thus, giving your consent to participate in this study also means that your coded medical data will be used for purposes described in this information form and that they will be transferred to the above-mentioned persons and/or institutions.

The sponsor may only use the collected data for this study.

The sponsor will use the collected data in the context of the study you are participating in, but would also like to be able to use them in other studies on the same disease as yours. This can only be done if an ethics committee has approved it.

If you have any questions about how we use your data, you can always contact the medical examiner.

Insurance

The sponsor is liable for any damage you as a participant may incur that is directly or indirectly attributable to your participation in this study, even if there is no fault. More information on this can be found in the parents' ICF.