

AUSTRALASIAN REGISTRY OF RARE AND GENETIC KIDNEY DISEASE (ARRK)

PATIENT INFORMATION SHEET (Parents and Guardians)

Title:	The Australasian Registry of Rare and Genetic Kidney Disease
Short Title:	ARRK
Protocol Number:	HREC Protocol Number: HREC/15/SCHN/517
Project Sponsor:	This research project is supported by an Enabling Grant from the Australian And New Zealand Society of Nephrology (ANZSN)
Coordinating Principal Investigator:	Dr Hugh McCarthy
Principal Investigators:	Professor Stephen Alexander, Dr Jeffery Fletcher, Dr Andrew Mallett, Dr Cathy Quinlan, and Dr Chirag Patel

We would like to invite your child to participate in a research study that aims to enable research into rare and genetic kidney diseases. This Participant Information Sheet and Consent Form tells you about the registry and what your child's participation would involve. It will help you to decide whether or not you would like your child to take part.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Participation of your child in this registry is voluntary.

What is the research about?

It is often difficult to find out about a rare disease. Doctors may not have diagnosed or treated such a condition before and clinical research is made more difficult because of this; and, sometimes progress in understanding the disease is slow. Patients too may experience difficulty finding out information about their illness.

The **Australasian Registry of Rare and Genetic Kidney Disease**, also known as **ARRK**, is an initiative of kidney specialists in Australia and New Zealand that aims to bring together as much information as possible from patients throughout Australia and New Zealand who have certain rare and/or genetic kidney diseases to enable us to gain a much better understanding of how these illnesses affect people.

How does the registry work?

Any adult or child who has a rare or genetic kidney condition is eligible to participate in this study.

If you agree to your child participating, clinical information about your child and their illness will be extracted from their medical record and compiled onto the ARRK database. Every six months your child's local kidney team will be contacted to request an update on your child's clinical information so that we can record any changes over time.

Any person who consents to participate in the registry will be given special access to the registry and you and your child will be able to see, at any time, all the information that is being collected about your child.

Doctors and scientists who are already actively researching your child's specific disease are working together as a group known as the **Disease-Specific Research Group (DSRG)**. An agreement has been signed between the DSRG and the ARRK such that they will only be able to access your child's clinical information once they have your consent. You will be informed prior to your consent being sought what information the DSRG would like. They will be able to view the data but not amend it. The DSRG may also contact you directly through the registry either to provide you with general updated information, or to invite your child to participate in additional research projects. By consenting for your child to participate in the registry, you are also consenting to the DSRG contacting you for this purpose.

What would I be agreeing to?

By consenting for your child to participate in the registry you are agreeing for your child's clinical information being held on a secure server operated by ARRK. You will be given a password that gives you secure access to your child's information

via the internet. You are also consenting to receive information from ARRK and the DSRG whilst your child's information is stored on the registry.

Your child's treating kidney specialist will also be aware your child is participating in the registry, and he or she will be notified automatically if the DSRG needs to make contact with you.

If your child is on the end stage renal program and you have already consented for your child to be on the ANZDATA registry, certain clinical data may be already entered onto this database. If you consent for your child to participate in ARRK data may be shared between the two databases to minimise duplication and to ensure accuracy of information.

ARRK will not share any of your child's personal information with any other organization unless you specifically consent to us doing so. Consenting for your child to participate in the registry does not commit your child to engaging in any of the research projects that might be proposed by the research group. Any research proposal will have the appropriate approval from a human research ethics committee as does this registry.

Who else will know my child is participating in the registry?

Your child's kidney specialist will know that your child is participating in the registry (ARRK). They will be responsible for entering your child's clinical information onto the registry. They will also be provided with feedback from the registry, and will be notified if the DSRG investigating your child's condition propose to make contact with you. If you agree, your child's GP will also be informed that your child is participating in the registry.

How secure is my child's clinical information?

The registry is designed so that all of your child's information will remain secure. Once your child's information has been uploaded to the system, it will be encrypted so that your child's personal details cannot be identified.

The database will be hosted and maintained by the Centre for Comparative Genomics, Murdoch University, WA using the Rare Disease Registry Framework (RDRF). This institute was chosen as they have extensive experience in the handling and storage of sensitive data and are the secure server for many other national registries.

Can I have time to think about this?

Yes, you can take as much time as you need. If you decide you would like your child to participate, we would ask that you sign and return the consent form.

What happens if I change my mind?

You can withdraw your child from the registry at any time without this affecting your child's relationship with the hospital or their kidney specialists at any time. If you would like to withdraw your consent for your child, you can do so by either writing to ARRK directly or your kidney specialist to make this change. If you withdraw your child, it may not be possible for information that has already been used in specific research to be withdrawn however you will receive no further contact from ARRK or DSRG.

Who is responsible for ARRK?

ARRK has been set up with the support of the National Kidney Research Organization known as the Australia and New Zealand Society of Nephrology (ANZSN) and the registry has been ethically reviewed and approved by the Sydney Children's Hospital Network Human Research Ethics Committee.

What happens when my child grows up?

When your child reaches age 16 years, they may wish to demonstrate their understanding of the study and willingness to participate by signing a Parent/Guardian consent form. When your child reaches 18 years of age, they will be required to consent for themselves, and so an Adult Participant Information Sheet and Consent Form will be sent to them. If your child does not consent for himself or herself to remain on the registry, they will no longer be contacted by ARRK or DSRG. They could reactivate their participation later if they wish.

Who can I contact for further information?

If you would like further information about the registry or have any concerns please discuss these with your child's kidney specialist. If you have any questions that they may not be able to answer, please contact the study lead, Dr Hugh McCarthy of the ARRK program at the address below.

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This research project has been approved by the Sydney Children's Hospitals Network Human Research Ethics Committee. If you have any concerns or complaints about the conduct of this research project, please do not hesitate to contact the Executive Officer of that Committee on 02 9845 3066 or via email SCHN-Ethics@health.nsw.gov.au and quote approval number HREC/15/SCHN/517. All enquiries will be handled in the strictest of confidence.