

National Registry of Rare Kidney Diseases (RaDaR)

Parent/Guardian Information Sheet

Thank you for taking the time to read this information sheet. This document is for parents of children under the age of 18 as well as legal guardians of those over the age of 18 who have limited capacity.

What is this research about?

The **National Registry of Rare Kidney Diseases (RaDaR)** is a research initiative by UK kidney specialists (the Renal Association and the UK Renal Registry). It is designed to gather information from patients with rare kidney diseases. This will give a much better understanding of how these illnesses affect people. It will help to improve treatment and identify possible causes of these rare diseases.

How does it work?

If you agree (consent) for your child/ward to take part, information about their treatment and any medications they are on will be entered into the RaDaR database by a member of your hospital's research team or electronically sent to RaDaR from your kidney unit. In a form that means they cannot identify you, known as pseudonymised data. "Pseudonymised" means that information which can identify you, such as your name, date of birth and NHS number is removed and replaced with a unique number which is used instead.

What would I be agreeing to?

Taking part in RaDaR means that you agree that relevant information about your child/ward's medical history can be held on a secure computer system operated by the UK Renal Registry. You can find out more about your child/ward's kidney condition on RareRenal.org, which is supported by the Renal Association and the Rare Disease Groups.

By joining this study you give permission for researchers to use your child/ward's past, present and future clinical data for ongoing and future ethically approved research into kidney disease and related conditions.

Data will be collected from a number of sources including:

- Their GP and hospital records
- **The UK Renal Registry** – collects data on patients with chronic kidney disease and those who are on renal replacement treatments such as dialysis or kidney transplant. This helps monitor standards of care across the country and will include data items such as dialysis sessions and transplant outcomes where applicable.
- **NHS Digital** – which collects, stores and analyses information from a variety of sources across the NHS. By taking part in RaDaR you agree for your child/ward's identifiable data (NHS number, Date of Birth and initials) to be sent to NHS Digital to link this information to two main databases:
 - **Hospital Episode Statistics (HES) in England** - this includes information about all hospital admissions, including when, why and for how long they happen. This will allow researchers to track the long term health of patients recruited to RaDaR.
 - Civil Registration services data - this includes information on patients who have died, including the date and cause of death. This will allow researchers to determine what happens to patients in

RaDaR and importantly to prevent any attempts at contacting those who are no longer alive, potentially causing unnecessary distress to relatives or friends.

- **HES equivalents in Wales, Northern Ireland and Scotland** – Wales (Patient Episode Database for Wales), Scotland (Information Services Division Scotland) and Northern Ireland (Health and Social care services Northern Ireland).
- **Public Health England** – which records details of anyone in the UK who is diagnosed with cancer and acquired infections.
- **Digital Patient Records** – which are online platforms that allow patients to view their medical records, as well as record symptoms, medications and other details. By taking part in RaDaR you agree that your child/ward's data from any digital patient records they may be signed up to (e.g. PatientView, Patient Knows Best etc.) may be shared with RaDaR.
- Any other **UK-based approved national research studies, registries or bio-banking schemes** that your child/ward has previously consented to and participated in, or will do so in the future. By consenting to RaDaR you agree that their identifiable data (including NHS number and Date of Birth) can be used to confirm their participation in such studies if this is permitted by their own Ethics approval.

Agreeing to take part in RaDaR doesn't mean you have to take part in any related research projects in the future if you don't want to.

Taking part in RaDaR is entirely voluntary. If you choose not to take part, it will not affect your child/ward's treatment or medical care in any way.

Why is this data needed?

As your child/ward's condition is rare, it is important that as much data as possible is gathered for analysis. Researchers may want to investigate if certain aspects of the condition (e.g. laboratory results or treatments) are associated with specific benefits or complications. By allowing the research team to link your child/ward's data with that gathered from other clinical studies, researchers will be able to study the long-term outcome of their condition and any treatments that they receive.

How will I be contacted?

You may occasionally be contacted by a member of the central RaDaR team or the Rare Disease Group lead for your child/ward's condition. This may include invitations to patient information days, details of further research studies that your child may be eligible to join or requests to re-consent to RaDaR if any changes are made in the future. Any such contact will be pre-approved by the RaDaR Operational Management Team(OMT) before it is sent to you. Occasionally, RaDaR may use an outside organisation to help prepare and send out these communications, especially when trying to communicate with a large number of patients at one time. Any outside organisation which is used for this purpose will be subject to a contract which sets out the limits of what they are allowed to do and will comply with the information governance standard as required by law. Organisations contracted by RaDaR will be considered data processors, meaning that they will use your child/ward's personal information on behalf of RaDaR (the data controller) for specific purposes set by RaDaR.

Your child/ward's pseudonymised data (data assigned a random number rather than your child/ward's name) may be shared with other researchers, including those from Universities and commercial companies, who are investigating their condition. Any such requests will be approved by the Renal Association, the OMT and the Lead Clinician of the relevant Rare Disease Group via a process which assesses the benefits and risks of the study for patients and which ensures that data is shared securely and in accordance with the law. Your child/ward will not be able to be identified or contacted by any of these researchers.

Will my child's/ward's kidney doctor know about this?

Yes. Their kidney doctor knows about RaDaR and can discuss it with you if you wish.

How secure is my child/ward's information?

Their data will be secure. Your child/ward's record will be given a unique identifier so that when analysis is undertaken the researchers will only know your child/ward's data by that number. They will not know any personal details. All RaDaR employees are carefully vetted and given security clearance according to their tasks. The Rare Disease Groups have signed a strict confidentiality contract with RaDaR in order to use it.

Can I have time to think about this?

Yes, you can take as much time as you need.

What happens if I change my mind?

You can withdraw your child/ward from RaDaR at any time. You could either contact RaDaR directly as below or talk to their kidney doctor. Your child/ward's information would no longer be updated and your family would not be contacted in the future.

Who can I speak to if I have any questions?

The RaDaR operations officer can help with many of your queries by using the email or telephone number below. Alternatively your child/ward's kidney doctor or kidney nurse may be able to help.

What happens when my child grows up?

When your child turns 16 they will be sent an information sheet about RaDaR and asked if they would like to continue to take part. If they do not consent for themselves before they turn 18 it will be assumed that they do not wish to remain in RaDaR. Their data will be no longer be updated and no further contact made. They could reactivate their participation later if they wish.

If you are consenting as a legal guardian of an adult over the age of 18 then this consent will remain and there will be no need to re-consent unless any changes are made to the study

Who is responsible for RaDaR?

RaDaR was set up as a joint initiative of the Renal Association, the British Association for Paediatric Nephrology and the UK Renal Registry. RaDaR is governed by the Renal Information governance Board of the Renal Association. The Registry has been approved by the South West – Central Bristol Research Ethics Committee, reference 19/SW/0173.



What happens if something goes wrong?

If you are concerned about RaDaR you should talk to your child/ward's kidney doctor. If you are still worried you can contact the RaDaR team at the address below.

RaDaR Operational Officer

UK Renal Registry

1st floor Brandon House,

Building 20A1,

Southmead Road,

Bristol,

BS34 7RR

Email address: nbn-tr.radar@nhs.net

Telephone number: 0117 4148150