Consent for Approach for Research (C4AR) Database
Relative/Friend/Carer of an Adult (16+) Instructions

If you have an adult (16+) relative, friend, or person you care for who would like to take part but needs support to give consent or complete the research questionnaires, you may assist them.

Your role is to support them in understanding the information and recording **their own answers**—not to answer on their behalf. The person taking part must have capacity (that is, be able to understand the information provided and make their own decisions). They must also be able to communicate their decisions and responses verbally so that you can accurately complete the consent form and questionnaires according to what they say.

Below is the adult information sheet that your friend or relative must read. If they are unable to read it themselves, please read it to them and check that they understand the content before they decide whether to take part.

Adult Participant Information Sheet

1. Introduction

The UK Kidney Association (UKKA) is a charity that supports healthcare professionals working to help patients and their families to live well with kidney disease. The UKKA stays connected with people whose lives are directly affected through a Patient Council. The experiences, views and opinions of the Council's patients can influence current and future kidney services because the UKKA works closely with kidney units, researchers and the NHS.

You might know that the UKKA already has a database. This is called the UK Renal Registry (UKRR). This contains useful clinical information like treatments and test results but does not focus on items of direct importance to patients such as fatigue and quality of life. Data comes directly from kidney units with permission from the NHS and special ethics approval. Patients cannot be contacted directly and therefore can't be informed about research opportunities. They can't tell us about their experiences, what is important to them and how they want their care and treatment to be improved.

2. What is this new research database about?

The members of the Patient Council feel strongly about making sure that everyone living with kidney disease has a voice and is given the opportunity to take part in research that is of importance to them. The Consent for Approach for Research (C4AR) Database has been set up to create a community of patients of all ages who are happy to be contacted about opportunities to take part in research. Being led by the UKKA Patient Council means that research is overseen by patients, for patients.

The C4AR Database is the first of its kind for kidney patients on a UK-wide scale.

3. Why am I being invited to take part?

You are reading this because you have seen an advert or have heard/been told about this database and have chosen to find out more. You are eligible to take part if you are aged 16 or over, have kidney

disease, and are currently receiving care from a hospital kidney team. We are inviting people who meet these criteria to help us better understand patients' experiences of kidney disease.

It is entirely up to you whether you decide to take part. Choosing not to participate will not affect your current or future care in any way.

4. What will happen if I choose to take part?

If you consent to take part, the UK Kidney Association (UKKA) will securely store your contact details and basic information such as your NHS number, date of birth, and treating hospital or unit. We will ask you to complete a short registration questionnaire about your current treatment and medications. We will also invite you to complete a brief wellbeing questionnaire every six months, which takes about 5–7 minutes and helps us monitor changes over time.

When a new piece of research begins, we will contact you by email (or via a phone message if you prefer) with an invitation to take part. Participating in each piece of research is voluntary, will be explained fully, and you will be asked to consent each time.

We will send you a newsletter twice a year telling you about research results and plans for new research. The newsletter and our webpage will share other information we think might be of interest to you (e.g. news on trials for new treatments and patient events).

It is important for you to understand that **taking part in the C4AR Database is entirely voluntary**.

5. What are the possible benefits of taking part?

The research conducted with your help is likely to improve care for people with kidney disease in the future. You will be kept informed of opportunities to participate in some research studies and clinical trials that have the potential to benefit you directly.

6. What are the possible risks of taking part?

This research is considered low risk. However, as with any study involving personal information and questionnaires, there are some potential risks, which are outlined below.

Data security

We store and manage your information in accordance with UK data protection law and use secure systems and strict access controls to protect your data. While data breaches are rare, no electronic system can be guaranteed to be completely risk-free. If a data breach were to occur that posed a risk to your rights or freedoms, we would investigate it promptly, take action to reduce any potential impact, and report it in line with legal requirements. Where required, we would inform you and provide advice about any steps you may need to take. To ensure confidentiality when conducting research, your name and personal details will be replaced with a unique study number so that you cannot be identified.

Possible emotional distress

Some questionnaires will ask about pain, fatigue, emotional wellbeing and daily functioning. A small number of people may find topics like these upsetting. You may stop a questionnaire at any time without giving a reason, and this will not affect your involvement in the database or future research.

If you feel distressed, you should contact your kidney care team, GP, or one of the support organisations whose contact details we will provide with the questionnaires. It is not appropriate for the research team to provide medical or crisis support. If you tell us that you are at immediate risk of

harm to yourself or others, we may need to share this information with appropriate services in line with UKKA safeguarding procedures.

7. Will you collect any other information about me?

By using the details you give us when you consent, we will be able to identify your records in our other databases, including the UK Renal Registry (UKRR). If you have a rare kidney disease and have already agreed to take part in the Rare Disease Registry (RaDaR), we will also be able to identify your records there. These databases contain clinical information that is routinely sent to us by your kidney unit.

For some research projects, we may wish to combine some of your information from these databases with new information you provide to us for the C4AR database. This helps us build a more complete picture of your kidney health and care over time without having to ask you to provide clinical information too. We will always ask for your permission before doing this, and you can choose whether to take part each time.

8. Will my information be kept safe?

Your information will be held securely by the UKKA. The UKKA collects, stores and uses your data in line with the requirements of the Data Protection Act (2018) (also known as the UK GDPR), as well as other laws which regulate the responsible use of data and protect your confidentiality.

Every year, the UKKA is accredited by the NHS to make sure that it has suitable systems and protections in place to keep your data secure and safe. Full details of how the UKKA processes patient data can be found in the Patient Privacy Notice. You can find a digital version on the UKKA website: https://www.ukkidney.org/patients/your-data

9. Will you share my information with anyone?

Only we will know who you are and only we will contact you. However, we would like to help other researchers with questions they believe are important to patients by sharing the data we collect. To access our data, external researchers must complete an application form. An internal panel of people will review this with the help of members of our Patient Council. If an application is approved, we have a well-established process in place for sharing data, using numbers instead of names, so that no participants can be identified.

10. Will my kidney doctor know about this?

We are telling all kidney units about the C4AR Database. However, we are not telling kidney doctors if the individuals they treat are part of the C4AR Database.

11. Can I have time to think about this?

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

12. What happens if I change my mind?

You can leave the C4AR Database at any time, without giving a reason. You can tell us directly and we will not contact you again. You will have the option to allow existing data to remain in the database to support ongoing/future research or to have this deleted.

13. Who can I speak to if I have any questions?

You can contact us using the postal or email address below.

14. Who is responsible for the C4AR Database?

The UKKA is responsible for the C4AR Database. The research will led by the UKKA Patient Council supported by an already established advisory group that includes patient representatives/advocates

from other key kidney charities and organisations. The database has been approved by an NHS Research Ethics Committee, and we will need to renew this approval every 5 years.

15. How can I ask questions?

If you have any questions, complaints or concerns, please contact us directly, either in writing or by email using the contact details below:

General contact:

C4ARD Study Team
UK Kidney Association
1st floor Brandon House, Building 20A1
Southmead Road
Bristol
BS34 7RR
Email address: C4ARD@ukkidney.org

Complaints or concerns:

Dr Zoe Plummer (UKKA C4ARD, Research & RaDaR Operational Lead)
Email address: zoe.plummer@ukkidney.org

Mr Tom Gray (UKKA Information Governance and Data Protection Officer)
Email address: tom.gray@ukkidney.org

Thank you for taking the time to read this information sheet