Participant Information Sheet

IRAS project ID 364008

Version 1.1 Date: 5 August 2026

PROTECT-Kidney: why do patients with kidney failure develop cognitive impairment?

PROTECT-Kidney sub-study: Exploring the effect of kidney disease on memory and brain health

Thank you for taking part in the PROTECT Study. We would now like to invite you to take part in the above sub-study led by researchers at the Exeter Kidney Unit and sponsored by the University of Exeter. Before you decide whether to participate it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Please ask a member of the research team if there is anything that is not clear or if you would like more information. Take your time to decide whether or not you wish to take part. If you decide to take part, you may keep this information sheet.

This study has been granted full ethical approval from the Preston Research Ethics Committee [reference 26/NW/0239].

What is the purpose of the study?

Previous research has suggested that memory problems and dementia are more common in people with kidney disease than in the general public. The reasons for this are still not well understood and we are researching this to better understand the problem.

By signing up for the PROTECT study you have already helped us to understand more about brain health in people with kidney disease. This study (PROTECT-Kidney) will give us even more information. This study will ask you a few questions about your kidney disease, it will sign you up to do the brain testing more frequently (every 6 months for the first two years, instead of every year), and it will give us permission to collect blood tests, either by taking an extra tube of blood when you next have blood tests, or by sending you a finger-prick pack in the post. This is so that we can measure levels of a protein called pTau217 that is being studied for its potential to predict whether people are likely to develop Alzheimer's disease.

We will use this information alongside the questions already included in the main PROTECT study to explore how kidney disease affects memory and brain health as people age.

Why have I been invited to take part?

You have been invited to take part because your responses to the questionnaires in the PROTECT study suggest that you have kidney disease, or because you were invited to the PROTECT study through the Exeter Kidney Unit or via promotional materials. We are giving you the opportunity to take part in this sub-study because it may help us to understand more about kidney disease and ageing.

Only participants from the PROTECT study with kidney disease are invited to take part in this sub-study.

Do I have to take part?

It is up to you to decide whether or not to take part in this sub-study. If you decide to take part, you are still free to withdraw at any time, without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your participation in the PROTECT Study and will not affect the care you receive from your kidney care team, or any other healthcare professionals.

What will happen if I take part?

If you choose to take part in the sub-study you will be asked to fill in a short questionnaire about your kidney disease, which will take approximately 5-10 minutes.

You will also then receive invitations to complete the brain tests offered by the PROTECT study a little bit more frequently (every 6 months for the first two years). These brain tests take around an hour to complete and can be done anywhere, including at home.

You will also be invited to give your permission for an extra tube of blood to be taken when you next have blood tests, or to complete a finger-prick check blood test at home, which will be used to check for levels of a protein called pTau217 that has been used to assess risk of Alzheimer's disease. These blood tests will be sent abroad to an accredited laboratory in Gothenburg, Sweden and will be link-anonymised, meaning the laboratory will not have access to your personal details but will be given a unique identifier number for your sample which will allow us to match your result to your record.

You will also give your permission for our study team (including a member of the Exeter Kidney Unit care team) to access your hospital records to gather information about your kidney diagnosis and treatments.

Your information will be added to your already collected responses as part of the main PROTECT study, which will help us to analyse how kidney disease affects with brain health and cognitive ability as people age.

What are the possible benefits and risks of taking part?

There is a very small risk that you may find the extra brain tests tiring, but they will still only be every 6 months. There is a very small risk that there will be issues collecting the extra blood sample, but as these samples are mostly being taken alongside routine blood tests, there will not be any extra needles or appointments for most participants. For those taking finger-prick blood tests at home, this involves a small prick compared with usual blood tests, and is also very safe. Although we will test your levels of a protein called pTau217 which has been used to assess risk of Alzheimer's disease, this test has not been explored in people with kidney disease so we will not know whether your test result will suggest a risk of Alzheimer's disease. Therefore, there is no chance that your test result will tell us that you have a higher risk of Alzheimer's disease, because this is early exploratory research.

The main advantage of this research is that participants will be taking part in an important study that could provide valuable new knowledge about how kidney disease influences health and cognition as people age. You will also be offered a £20 shopping voucher to compensate you for your time.

How will we use information about you?

We will need to use information from you and from your medical records for this research project.

This information will include your name, initials, NHS number and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

The University of Exeter is the sponsor of this research.

The University of Exeter is responsible for looking after your information. We will not share your information related to this research project with any other organisations.

We will keep all information about you safe and secure by:

- storing it on a secure password-protected University-based cloud server
- only giving a very small and select group of individuals access to your personal data (other researchers will only be able to view your pseudonymised information, from which you cannot be identified)
- complying with guidelines and legal frameworks about the way we store your data

International transfers

Your data will not be shared outside the UK.

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 15 years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital records. If you do not want this to happen, tell us and we will stop.

You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- our leaflet (www.hra.nhs.uk/patientdataandresearch)
- by asking one of the research team
- by sending an email to informationgovernance@exeter.ac.uk or

- by ringing us on 01392 725010.

What if I change my mind about taking part?

Your decision to participate in this study is voluntary. You can withdraw from the study at any time without giving a reason by logging into your PROTECT Study account and clicking on the Withdraw from Study option in the Manage Account section of the website. Alternatively, you can contact the PROTECT Study helpdesk by emailing support.protect@exeter.ac.uk or by telephoning 01392 725010.

By withdrawing you are making the decision not to provide any further information or responses to the study questionnaire and you will not receive any further communications about it. However, if you withdraw from the study, we will retain all anonymised data that we have collected up to the time you withdraw. This includes all anonymised data from questionnaires.

Who is organising this study?

This sub-study is being led by researchers at Exeter Kidney Unit, nested within the main PROTECT Study, which is led by the University of Exeter, King's College London and South London and Maudsley NHS Trust.

Contact for further information

If you have any questions or there is anything you wish to discuss, please contact the Chief Investigator Dr Robert Kimmitt (r.kimmitt2@exeter.ac.uk).

The Sponsor for this study is the University of Exeter. The Sponsor representative is: Suzy Wignall, Senior Clinical Research Governance Manager, University Research Services, Innovation Centre, Rennes Drive, Exeter EX4 4RN Email: res-sponsor@exeter.ac.uk

What if there is a problem?

If you are not happy with any aspect of the project and wish to complain please contact Dr Robert Kimmitt (r.kimmitt2@exeter.ac.uk). Alternatively, if you wish to contact someone outside the research team, please contact Suzy Wignall (res-sponsor@exeter.ac.uk).

Additional information and Frequently Asked Questions are available on the PROTECT Study website. If this does not answer your query you can contact the PROTECT Study team by calling 01392 725010.

Thank you for reading this information sheet and for considering taking part in this research.

Consent to Take Part

- I confirm that I have read and understand the Participant Information Sheet version 1.1 dated 5/8/2026 for the above sub-study, led by Exeter Kidney Unit and sponsored by the University of Exeter. I have had the opportunity to consider the information and ask questions, which have been answered satisfactorily.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.
- I consent to the processing of my personal information for the purposes explained to me via the Participant Information Sheet. I understand that such information will be handled and stored in accordance with the General Data Protection Regulation (GDPR) and other Data Protection Laws.
- I give my consent for a blood sample to be collected and analysed for pTau217 as part of this study. This may involve collection of an additional blood sample during routine clinical blood tests or, where this is not possible, collection of a small finger-prick blood sample using a home testing kit.
- I give my consent for researchers attached to Exeter Kidney Unit to collect data from my hospital record to be anonymised and analysed along with information already being collected about me from the PROTECT Study.
- I give my consent for the researchers to access relevant information already being collected about me from the PROTECT Study.
- I give my consent to be invited to complete extra memory and thinking tests, every 6 months for 2 years.
- I understand that my information may be subject to review by authorised individuals from the University of Exeter for monitoring and audit purposes.
- If I choose to withdraw, I understand that all anonymised data will be retained in the study up to the point of my withdrawal, and no further data will be collected.
- I agree to take part in PROTECT-Kidney