Principal Investigator: Dr Edward Sharples
Oxford University Hospitals
Email: edward.sharples@ouh.nhs.uk
Tel: +44 (0)1865 225355/6

PARTICIPANT INFORMATION SHEET

Assessing Donor Kidneys and Monitoring Transplant Recipients **(ADMIRE)**

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information and discuss it with others if you wish. If there is anything that is not clear or if you would like more information, please ask us.

Summary (Key Facts)

- ***Purpose of the study:*** To assess the feasibility and potential of evaluating donor kidneys using advanced MRI scanning techniques before and after transplantation.
- ***Participants:*** Adult kidney transplant living donors and recipients, as well as deceased donor kidney offers and their recipients at Oxford University Hospitals (OUH).
- ***Study Procedures:*** MRI scans of donor kidneys (before transplantation) and of the participating recipients (3 months after transplantation).
- ***Possible Risks and Benefits:*** MRI scans are safe but may involve minor discomfort. The study aims to improve kidney transplant outcomes for future patients.

What is the purpose of the study?

- Kidney transplants are a life-saving treatment for people with end-stage kidney failure. However, some donor kidneys are at higher risk of not functioning well or not at all after transplantation. This study aims to use advanced MRI scanning techniques to better predict and monitor kidney function, which would help improve outcomes for future transplant recipients.

Why have I been invited?

- You have been invited because you are receiving a kidney transplant at Oxford University Hospitals (OUH). We are seeking to involve 15 patient (recipient) participants, 10 deceased donors and 5 living kidney donors in total for this study.

Do I have to take part?

- No, taking part is entirely voluntary. If you decide not to take part, or if you change your mind later, you do not need to give any reason, and this will not affect the care you receive.

What will happen to me if I decide to take part?

- A researcher will meet you to go over the information sheet, explain what you would need to do, and go through a screening form with you to check if it is safe for you to participate. If you are suitable and agree, we would ask you to come to the radiology department in Oxford University Hospitals for the study scan*.* Before you come to your visit, please let us know if you wear contact lenses or glasses.
- One of our research team would meet you to review what participation will involve and answer any questions you may have. If you are happy to continue, they will then ask you to sign a consent form.
- If you agree to participate, the study will involve the following:

1. **Pre-Transplant (Donor Kidney MRI):** Once a donor kidney arrives at OUH (or after it is removed surgically from a living donor), it will undergo an MRI scan to assess its condition before transplantation. This scan is purely for research purposes.
2. **Post-Transplant MRI:** About 3 months after your transplant, you will have an MRI scan of your transplanted kidney. We will endeavour to schedule this scan on the same day of your standard follow-up clinic appointment. This scan is going to be purely for research purposes. On arrival for your scan, someone will go through the MRI Screening Form with you again to make sure that it is still safe for you to take part. You would be asked to lie still on a table inside the MRI scanner while having a series of MRI scans over a period of about 60 minutes. The entire research visit will last for up to 2 hours. If someone comes with you, the research team can show them to an area where they can wait.
3. **Data Collection:** We will collect clinical details about your health and transplant outcomes, such as blood and urine test results, and kidney function metrics at several key stages: at time of transplantation, 2 weeks and 3 months after your transplantation during your follow-up visits and 12 months after your transplantation from the NHSBT registry, The entire research period will last about 12 months. Both 2 weeks and 3 months data collection will coincide with the routine clinical visits.

What should I consider?

- This study involves non-invasive MRI scans. If you have a pacemaker, metal implants, or tattoos, you may not be eligible for the scans.

- If you are unwilling or unable to comply with the requirements of this protocol or have any condition (physical, mental, or social) that, in the opinion of the investigators, is likely to affect your ability to comply with the study protocol, you may not be eligible for participation in this study.

- If you are pregnant or think you may be pregnant, you should not take part in this study.

Are there any possible disadvantages or risks from taking part?

- MRI is safe and does not involve any ionising radiation (x-rays). However, because it uses a large magnet to work, MRI scans are not suitable for everybody. You would be asked to answer some safety questions to determine if you can take part. Normally, we would need more information before you take part in the research MRI scan if you have a heart pacemaker or stent, mechanical heart valve, mechanical implants such as an aneurysm clip, joint replacement (e.g., hip/knee), or if you carry other pieces of metal that have accidentally entered your body.
- While there is no evidence that MRI is harmful to unborn babies, as a precaution, the Department of Health advises against scanning pregnant women unless there is a clinical benefit. We do not test for pregnancy as routine on the day of the scan, so if you think you may be pregnant you should not take part in this study.
- While very rare, tattoos can occasionally warm up in the scanner. Please inform the person operating the scanner immediately if you feel any heating. If you have a new tattoo, you should not take part in a scan until 48 hours after receiving the tattoo.
- If you think you might be claustrophobic, please talk to the researcher in advance, or let the person operating the scanner know before you start.
- Some of the scans are noisy, so we will give you earplugs to make this quieter for you. It is important that these are fitted correctly, as they are designed to protect your hearing.
- In preparation for your scan, you will be asked to refrain from eating or drinking for the two-hours preceding the MRI scan, and for your comfort and safety we may ask you to change into scrubs ("pyjama-style" top and trousers), available in a range of sizes. You may keep your underwear and socks on, but you will need to remove underwire bras. If you have a suitable non-wired bra, you may wear this instead. Do not wear any fabrics that contain metallic threads or are silver impregnated (often marketed as anti-microbial/bacterial or anti-odour/stink). Metal jewellery, including body piercing, must also be removed. If you wish to wear eye makeup to your scan, we will give you makeup removal wipes because you should not wear eye shadow or mascara in the scanner. If you wish, bring your own makeup to reapply. Lockers are provided to secure your personal belongings and clothing.
- You will be introduced to the scanner carefully and allowed to leave at any stage. Whilst in the scanner you will have a call button, which you can press if you need to stop the scan or speak with the person operating the scanner.
- It is important to note that we do not carry out scans for diagnostic purposes, only for research. Our scans are not routinely looked at by a doctor and are therefore not a substitute for a doctor's appointment. Occasionally, however, a possible abnormality may be detected. In this case, we would have the scan checked by a doctor. If the doctor felt that the abnormality was medically important, you would be contacted directly, and further assessment arranged as necessary. You would not be informed unless the doctor considers the finding has clear

implications for your current or future health. All information about you is kept strictly confidential.

What are the possible benefits of taking part?

- While there are no direct benefits to you or your donor, this research may help improve the assessment and monitoring of kidney transplants for future patients.

Will my General Practitioner (GP) be informed of my participation?

- Your GP will not be informed unless a clinically significant finding requires follow-up.

Will my taking part in the study be kept confidential?

- Yes. All study records and samples will be identified only by a code. We will only use your name, date of birth, and hospital record number, where this is necessary, to contact you. Information that can identify you will only be held securely by the local team at Oxford University Hospitals, on a password protected computer for the purposes of the study.
- Confidentiality will be maintained as far as it is possible, unless you tell us something which implies that you or someone you mention might be in significant danger of harm. In this case, we would have to inform the relevant agencies, but we would discuss it with you first.
- Responsible members of the University of Oxford, regulatory authorities and Oxford University Hospitals may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.
- MRI data may remain potentially identifiable due to its nature.
- All research data collected during this study will be kept for at least 7 years after the study ends. Personal data will be only kept at site for a maximum of 12 months after the study ends, to ensure the needs for monitoring and quality control are met.

Will I be reimbursed for taking part?

- You will not be paid for participating in this study, but reasonable travel expenses for study visits will be reimbursed if we are not able to arrange them to coincide with your clinic appointments.

What will happen to the samples I give?

- No biological samples will be collected as part of this study.

What will happen to my data?

Data protection legislation requires that we, the University of Oxford (whose legal name is The Chancellor Masters and Scholars of the University of Oxford), state the legal basis for processing information about you. In the case of research, this is a 'task in the public interest'. The University of Oxford is the sponsor for this study and is responsible for looking after your information and using it properly.

We will need to use information from you, from your medical records and your hospital records and the NHSBT registry for this research project. We will share your year of birth and the code number

assigned to your data related to this research project with the following types of organisations, the University of Nottingham, NHS organisations.

This information will include your

- Participant ID
- Year of birth
- Name
- NHS Number
- 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.

Your personal data will not be shared outside the UK. 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 the minimum period of time required the University of Nottingham policy for imaging data (MRIs), which the University of Oxford will follow for all research data for this study.

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. You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. 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.

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

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

- asking one of the research team.
- sending an email to maria.kaisar@nds.ox.ac.uk
- contacting the University's Data Protection Officer data.protection@admin.ox.ac.uk
- looking at the University's privacy notice available at: How we use your personal data for research purposes | Compliance (https://compliance.admin.ox.ac.uk/data-protection-policy).

If you would like to find out more about the use of confidential data in research, the HRA has developed a general information leaflet which is available at: Patient data and research leaflet -

Health Research Authority (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/).

The Oxford University Hospitals team will use your name, NHS number and contact details, to contact you about the research study, and to oversee the quality of the study.

A copy of the consent form from this study will be kept in your medical records for as long as those records are retained.

Authorised MRI scanning centre personnel at Oxford University Hospitals and the research team at the University of Oxford and the University of Nottingham will have access to the MRI imaging data. MRI imaging data is assigned a unique ID and your year of birth as it is collected and stored in a secure database on university managed IT systems. Due to the nature of the MRI images, they remain potentially identifiable, even after we destroy your personal details. Imaging data will be stored on archive tapes at the MRI location and kept indefinitely, for quality control, and to facilitate further use of the scans where permission has been given.

What will happen to the results of this study?

- The results will be published in medical journals and presented at conferences. The data may be shared with other researchers in a way that does not identify you. You will not be identified in any report or publication. If you request a summary of the findings, you can contact the research team and we can provide this once the study ends.

What will happen if I don't want to carry on with the study

Participants may choose to stop the study assessments but may remain as a participant.

Participants may also withdraw their consent, meaning that they wish to withdraw from the study completely. Participants may have the following options for withdrawal:

- Participants may withdraw from active follow-up and further communication but allow the study team to continue to access their medical records and any relevant hospital data that is recorded as part of routine standard of care, i.e., CT-Scans, blood results etc and registry data
- Participants can withdraw from the study but permit data obtained up until the point of withdrawal to be retained for use in the study analysis. No further data or samples would be collected after withdrawal.

  Participants can withdraw completely from the study and withdraw the data collected up until the point of withdrawal. The data already collected would not be used in the final study analysis, if possible, at point of withdrawal. If not possible, we will tell you why we cannot do this.

What if we find something unexpected?

- Our MRI scans are not for diagnostic purposes. However, if an abnormality is found that may affect your health, a doctor will review it and inform you and your GP when necessary.

What if there is a problem?

- If you have a concern about any aspect of this study, please speak with the clinical or research team. They will do their best to answer your questions.
- The investigators recognise the important contribution that volunteers make to medical research and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor can advise you of further clinical action and refer you to a doctor within the NHS for treatment, if necessary.
- NHS indemnity operates in respect of the clinical treatment provided.
- If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, contact Dr Edward Sharples via telephone or email listed above or you may contact University of Oxford Research Governance, Ethics & Assurance (RGEA) at rgea.complaints@admin.ox.ac.uk or on 01865 616480.
- The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study.
- If you wish to contact the PALS team, please contact 01865 221473 or PALS@ouh.nhs.uk.

How have patients and the public been involved in this study?

- Service users helped develop the research topic and what research questions should be asked and will continue to be involved in the study.
- In designing this study, we have received patient advice on the frequency of participant visits and the tests that we will carry out.
- Potential participants were involved in describing the inclusion and exclusion criteria for this study.
- If you have concerns about any aspect of the study, please contact the study team (details below). In the unlikely event of harm caused by participation, you may be eligible for compensation through the University of Oxford's insurance.

Who is organising and funding the study?

- This study is funded by Kidney Research UK.
- This study is sponsored by the University of Oxford.
- University of Nottingham is a collaborator.
- Oxford University Hospitals is the only site.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion by < _____> Research Ethics Committee.

Participation in future research:

All contact will come from the clinical team of the Oxford transplant centre or a member of the research team of this study in the first instance, agreeing to be contacted does not oblige you to take part in future research, and you can be removed from this register at any time they wish. Your contact details would be held securely, separately from this study at the Oxford Transplant Centre on a password protected computer accessible by authorised individuals from your clinical team.

Further information and contact details:

- **Chief Investigator:** Assoc. Prof. Maria Kaisar, email: maria.kaisar@nds.ox.ac.uk
- **Principal Investigator:** Dr Edward Sharples, email: edward.sharples@ouh.nhs.uk

Thank you for considering taking part.