## Appendix 3: Participant Information Sheet

**Introduction**

You are invited to participate in a study assessing the utility of an advanced recovery model, with more intensive monitoring after your living donor kidney transplant operation.

**What is the purpose of the study?**

The care of your new kidney, in the first 24 hours of the operation, is very important. Parameters such as your blood pressure, the amount of fluid we give you and the amount of urine you make all have an impact on how well your new transplant kidney works in the immediate post operative period. Optimisation of these parameters may have an impact on the long-term function of your graft.

This is a pilot study looking at different way that you can be monitored after your kidney transplant. The study would aim to compare our current protocol against additional methods of monitoring your blood pressure and fluid status, to see if this leads to better outcomes.

**What does the study involve?**

This study is a randomised trial. If you agreed to participate, you will be randomised to 1 of 2 post operative care models.

One model is the current standard Royal Adelaide Hospital post transplantation management protocol, which will involve you being managed on the kidney ward (ward 7F) with a team of kidney doctors and nurses after time spent in recovery.

The second model will involve you being admitted to a specialised advanced recovery area for 24 hours after your kidney transplant. You will have regular observations and occasional blood tests. The study may require the placement of an arterial line, which is a line that can be used for intensive blood pressure monitoring and blood taking without the need for additional venepuncture. After the operation, you will be monitored carefully by a team consisting of kidney doctors, recovery nurses and kidney nurses trained in post-transplant care. After 24 hours, you will move to the kidney ward.

**Who is undertaking the research?**

The research study is being conducted by a team of researchers that are part of the Clinical Research Group within CNARTS (listed below).

**Dr Karthik Venkataraman**

Renal Advanced Trainee, Central and Northern Adelaide Renal and Transplantation Service

Email: Karthik.venkataraman@sa.gov.au

**Dr Michael Collins**

Senior Nephrologist, Central Adelaide Local Health Network

Email: Michael.collins@sa.gov.au

**Professor Toby Coates**

Senior Nephrologist, Central Adelaide Local Health Network. Professor of Medicine, University of Adelaide. Director of Kidney and Islet Transplantation, Central Adelaide Local Health Network

Email: toby.coates@sa.gov.au

**5. What changes will be made to my care if I decide to enter the study?**

If you are allocated into the control arm, your care will be the same high level of care we provide to all transplant recipients. This would involve close monitoring in a ward based environment.

If you are allocated to the treatment arm, your clinical care will take place in the Advanced Recovery Room, on level 4 of the Royal Adelaide Hospital, and will included extra monitoring, with the possible addition of extra blood testing. You may have an arterial line placed in your wrist. You may receive medications to increase your blood pressure if it drops too low. It should be noted that this medication is current standard of care and you may receive it even if you don’t enrol in the study, should your blood pressure drop after the kidney transplant.

**6. What if I choose not to enter the study?**

This is a research project and you do not have to be involved. If you choose not to participate, your medical care will not be affected in any way.

**7. What if I enter the study and then change my mind?**

You may withdraw from the study at any time.

**8. What are the benefits of the study for me?**

The aim of the project is to improve the care of patient undergoing kidney transplantation. As a part of this study, you may be more intensely monitored in the first 24 hours than standard of care.

**9. What benefits will the study have to the community?**

We hope that this project will improve our understanding of low blood pressure on kidney function immediately after transplantation and will allow us to improve the care of all patients undergoing kidney transplantation.

**10. Will I be inconvenienced in any way by being in the study?**

You may be inconvenienced by having an arterial line placed in your arm, usually in your wrist. You may be inconvenienced by the frequency of observations.

**11. Are there any foreseeable risks associated with being in the study?**

The study will increase the intensity of monitoring after your kidney transplant. While this is likely to have an overall benefit to you, it may cause inconvenience. The risks of arterial line placement include risk of injury to the radial artery, an artery in the risk. Importantly, this may impact on your ability to have an arteriovenous fistula for dialysis in the future

**12. Who will have access to my responses?**

The information collected in this study will only be available to the clinical research team involved with this study. You will not be identifiable within the analysis of the group data. De-identified data will used by the University of Adelaide study investigators. Your data may be used in research that arises from this study but your individual details will not be transferred.

**13. How with the data be stored?**

All paper based data collected will be stored securely within CNARTS, and only able to be accessed by the study team. Electronic data will be stored on a secure SA Health database and will only be able to be access by trial investigators and authorised users. Data will be stored for a period of five years from the date of publication.

**14. Can anyone else access the data?**

In addition to the processes described above, data may otherwise be discoverable through processes of law or for assessing compliance with research procedures.

**15. What if I want to access my responses?**

You have the right to access the information collected and stored by researchers about you. You have the right to request that any information with which you disagree be corrected.

**16. Who can I contact if I have concerns?**

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007) incorporating all updates. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any medical problems which be related to your involvement in the project, you can contact the principal study doctor via email Karthik.venkataraman@sa.gov.au or mobile 0430495079.

The study has been approved by the Central Adelaide Local Health Network Human Research Ethics Committee. If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or about the conduct of the study, you may also contact the CALHN HREC Chairperson, on 7117 2229.

## Appendix 4: Patient Consent Form

**Consent Form**

|  |  |
| --- | --- |
| **Title** | Pilot Randomised Controlled Trial of Personalised Goal Directed Therapy after Living Donor Kidney Transplant. |
| **Protocol Number** | TBA |
| **Project Sponsor** | Kidney, Transplant and Diabetes Research Australia |
| **Principal Investigator** | Dr Karthik Venkataraman |
| **Associate Investigator(s)** | Dr Michael Collins, Prof. Toby Coates |
| **Location** | Royal Adelaide Hospital |

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the Central Adelaide Local Health Network concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

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| --- |
|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
|  |

|  |
| --- |
|  |
|  | Name of Witness\* to Participant’s Signature (please print) |  |  |
|  |
|  | Signature |  |  Date |  |  |
|  |

\* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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|  |
|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.