Health
South Eastern Sydney
Local Health District

Department of Renal Medicine, St George & Sutherland Hospital

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

The development of a web-based Chronic Kidney Disease Outreach Program: improving clinical outcomes of CKD patients in the St George and Sutherland area. (CKD CDOP study)

Invitation

You are invited to participate in a research study looking at chronic kidney disease management.

The study is being conducted by Professor Ivor Katz in collaboration with all the nephrologists of St George, Sutherland hospitals and GP services surrounding this area.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. 'What is the purpose of this study?'

The purpose of this study is to investigate better ways of early detection, monitoring and treatment of chronic kidney disease (CKD).

2. 'Why have I been invited to participate in this study?'

You are eligible to participate in this study because you have, identified risk factors that can lead to CKD or have been diagnosed of CKD.

3. 'What if I don't want to take part in this study, or if I want to withdraw later?'

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

You will be kept informed of any significant new findings that may affect your willingness to continue in the study.

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

However, it may not be possible to withdraw your data from the study results if these have already had your identifying details removed.

4. 'What does this study involve?'

If you agree to participate in this study, you will be asked to sign the Participant Consent Form.

This study will be conducted over 3 years.

If you have low risk of CKD, you will be managed by a renal doctor and a renal nurse. You will be regularly monitored in conjunction with your GP.

If you have high risk of CKD you will be assigned randomly (by chance alone) to see a nephrologist in person or to an online nephrologist. The term "online nephrologist" means that your progress will be monitored by a nephrologist as the results of your tests are entered by your doctors or nurses from your surgery. This will not affect your care in anyway. You will be monitored on a regular basis and you will be able to see a renal physician if your renal function declines regardless of your allocated group.

Your medical information will be obtained from your local doctor and from the hospital medical records.

5. 'How is this study being paid for?'

The study is being funded by the Renal department. If we get any future sponsors for this study, all the money being paid by the sponsor to run the trial will be deposited into an account managed by renal department. No money is paid directly to individual researchers.

6. 'Are there risks to me in taking part in this study?'

All medical procedures involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable.

Physical risk is very low and involves discomfort that may be experienced during routine blood collection and blood pressure measurements.

7. 'What happens if I suffer injury or complications as a result of the study?'

If you suffer any injuries or complications as a result of this study, you should contact the study doctor as soon as possible, who will assist you in arranging appropriate medical treatment.

If your injury or complications are not of the kind set out under the heading *'Are there any risks to me taking part in this study?'* you may have a right to take legal action to obtain compensation, but only for serious injuries or consequences caused by the negligence of one of the parties involved in the study (for example, the researcher, the hospital, or the treating doctor).

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

8. 'Will I benefit from the study?'

This study aims to reduce the waiting time to see a nephrologist and to improve on early identification of risk factors and ongoing monitoring of CKD patients.

9. 'Will taking part in this study cost me anything, and will I be paid?

Participation in this study will not cost you anything.

10. 'How will my confidentiality be protected?'

The people, who are treating you, will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or as required by law. Your treating nephrologist, GP and the researchers involved in this study will have access to your details and results. All information will be held securely at a locked unit in the renal department.

11. 'What happens with the results?'

If you give us your permission by signing the consent document, we plan to discuss/publish the results

In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish.

12. 'What should I do if I want to discuss this study further before I decide?'

When you have read this information, the researchers Dr Jennifer Robins or Saiyini Pirabhahar will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact Jennifer or Saiyini on 91132484 or you can contact the principal investigator Prof Katz on 91132622.

13. 'Who should I contact if I have concerns about the conduct of this study?'

This study has been approved by the South Eastern Sydney Local Health District Human Research Ethics Committee (Southern Sector).

Any person with concerns or complaints about the conduct of this study should contact the Research Support Office, which is nominated to receive complaints from research participants. You should contact the office on 9113 2481 or 9113 2027 or via email: CentralEthics@sesiahs.health.nsw.gov.au and quote [*HREC/11/STG/232*].

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

CONSENT FORM

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1. I,.....
of.....
agree to participate in the study described in the participant information statement set out above.

2. I acknowledge that I have read the participant information statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the study, and the statement has been explained to me to my satisfaction.

3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.

4. I understand that I can withdraw from the study at any time without prejudice to my relationship to the South Eastern Sydney Local Health District.

5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

6. I understand that if I have any questions relating to my participation in this research, I may contact Dr Katz on telephone 91132622, who will be happy to answer them.

7. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.

Complaints may be directed to the Research Support Office, St George Hospital, Gray Street, Kogarah NSW 2217. Telephone (02) 9113 2481 or 9113 2027 or via email: CentralEthics@sesiahs.health.nsw.gov.au

Signature of participant	**Please PRINT name**	**Date**
_____	_____	_____
Signature of witness	**Please PRINT name**	**Date**
_____	_____	_____
Signature of investigator	**Please PRINT name**	**Date**
_____	_____	_____

Department of Renal Medicine, St George Hospital

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REVOCATION OF CONSENT

I wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with South Eastern Sydney Local Health District.

Signature of participant	**Please PRINT name**	**Date**
_____	_____	_____

The section for Revocation of Consent should be forwarded to **Associate Professor Ivor Katz, Department of Renal Medicine, 50 Montgomery Street, Kogarah, NSW 2217.**