

**Participant Information and Consent Form (PICF)**

**Non-Interventional Study**

**Title**  **“*Improving the self-management for people with chronic***

 ***kidney disease through a patient activation approach”***

**Protocol number**

**Principal Investigator** Laura Lunardi

**Associate Investigators** Anne Britton

 Monique Borlace

 Dr Richard Le Leu

 Dr Andie Xu

 A/Prof Paul Bennett

 A/Prof Shilpa Jesudason

**Location** **Central Northern Adelaide Renal and Transplant Service (CNARTS)**

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research project “***Improving the self-management for people with chronic kidney disease through a patient activation approach”***. This is because you have identified as having kidney problems and receive care by the renal team at CNARTS. This research project aims to identify how well you understand and manage your own health. This study includes only two short questionnaires that will help us to understand your health care needs to manage your kidney disease.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the research that is involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor.

This is a research project and you do not have to be involved. If you do not wish to participate, your medical care will not be affected in any way. Also, you may withdraw from the project at any time after you have commenced.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to the research that is described

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

**2 What is the purpose of this research?**

Chronic kidney disease can affect your general wellbeing. It is essential for you to take an active role in your health care. Being active in your health care, will reduce the impact of your kidney disease, will help you to delay the progression of your chronic disease, will improve your quality of life and will help you to live longer.

This research project aims to identify:

* How much you know and confident you are in managing your kidney problem
* Any individual factors that can affect your active role in your health care
* how well the recommendations from your health professionals are helping you to stay healthier

Identifying a potentially unmet need for your kidney problem; would lend support to greater healthcare resources being allocated to this area in the future.

**3 What does participation in this research involve?**

Consent form

The consent form, which follows this information, will need to be signed before any study assessments are performed.

Procedures

This research involves answering two simple short questionnaires. The questionnaires will be undertaken in person or over the phone and one of the researchers will ask you the questions. The survey is expected to less than 15 minutes to complete. There is no follow-up required.

How the research will be monitored

The only request is answers to brief questions and no further monitoring will be required.

Commitment required by the participant

A time commitment of approximately 15 minutes is expected.

Access to personal records

Access to your medical records will be required as part of this study. This information will be de-identified.

Bias

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

Additional costs & reimbursement

There will be no costs associated with participating in this research project, nor will you be paid. The researcher will see you during a planned treatment time or telephone you.

It is not expected that you will incur any personal expenses as a result of participating in this research project.

**4 What do I have to do?**

Answer the survey questions honestly and to the best of your knowledge.

**5 Other relevant information about the research project**

This research project involves only people receiving care by the Kidney Care Program at Central Northern Adelaide Renal & Transplant Service (CNARTS).

**6 Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Central Northern Adelaide Renal & Transplant Service.

**7 What are the alternatives to participation?**

You do not have to take part in this research project to continue to receive treatment at this hospital.

**8 What are the possible benefits of taking part?**

There will be no clear benefit to you from your participation in this research.

**9 What are the possible risks of taking part?**

There are no foreseeable risks associated to this study.

**10 What if I withdraw from this research project?**

If you decide to withdraw from this research project, please notify a member of the research team. There are no impacts to your continuing care by CNARTS and there are no special requirements linked to withdrawing.

**11 What happens when the research project ends?**

Once all the information is collected the research team will analyse the data and prepare a report. It is also planned that the document will be submitted to a medical journal for publication. There will not be any identifying information in any of these reports that might potentially identify you or any other participants.

**Part 2 How is the research project being conducted?**

**12 What will happen to information about me?**

By signing the consent form, you consent to the relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your survey answers will be de-identified and securely stored. Only the investigators will have access to this data, which will be kept for a period of 7 years and then destroyed. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the research team accessing health records if they are relevant to your participation in this research project.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

In accordance with relevant Australian and/or South Australian privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

**13 Complaints**

Any complaint that arises during the research regarding your treatment by staff should be directed toward Laura Lunardi on (08) 70745441 or laura.lunardi@sa.gov.au.

Your participation in this study shall not affect any other right to compensation you may have under common law.

**14 Who is funding the research?**

This research is being funded by the RAH Research Committee - 2022 RRC Allied Health, Pharmacy and Nursing Clinical Research Grant.

**15 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Central Adelaide Local Health Network.

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

**16 Further information and who to contact**

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 may be related to your involvement in the project, you can contact the principal study doctor on (08) 70745441 or any of the following people:

 **Clinical contact person**

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

|  |  |
| --- | --- |
| Name | Laura Lunardi |
| Position | Principal Investigator; Nephrology Nurse Practitioner  |
| Telephone | (08) 70745441 |
| Email | laura.lunardi@sa.gov.au |

**Complaints contact person**

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

|  |  |
| --- | --- |
| HREC Name | Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC) |
| Contact | HREC Support Officer |
| Telephone | (08) 7117 2229 |
| Email | Health.CALHNResearchEthics@sa.gov.au |



**Consent Form**

**Title** “*Improving the self-management for people with chronic kidney*

*disease through a patient activation approach”*

**Protocol number**

**Principal Investigator** Laura Lunardi

**Associate Investigators** Anne Britton

 Monique Borlace

 Dr Richard Le Leu

 Dr Andie Xu

 A/Prof Paul Bennett

 A/Prof Shilpa Jesudason

**Location** Central Northern Adelaide Renal and Transplant Service (CNARTS)

**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 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 project without affecting my future health care.

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

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to CNARTSconcerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.

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

**Declaration by 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.

|  |
| --- |
|  |
|  | Name of Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

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

Note: All parties signing the consent section must date their own signature.

**Central Northern Adelaide Renal and Transplantation Service (CNARTS)**

**“Patient Activation Project”**

 **Form RC - Remote Informed Consent Confirmation Form - Australia**

Please complete this form when a potential participant undertakes the informed consent process for the Patient Activation Study via telehealth or telephone.

**Reporter’s Signature**

**Name**

**Signature**

**Date signed** | | |**-**| | |**-**| | | | |

It documents the flow of the informed consent progress (before and/or after participant review of the Patient Information and Consent Form PICF). The participant must be given sufficient time to read PICF and ask questions.

No study activities are to be undertaken until a hard or electronic copy of the consent form is received by the site and signed by Investigator or delegate (on the receipt date at site). Please store this form with the fully signed PICF and upload both to the participant’s medical records (as required). A copy of the completed PICF should be forwarded to the participant.

***Participant signed the PICF***

***The PICF was receipted by the site:***

**Date signed**

| | |**-**| | |**-**| | | | |

**Date**

| | |**-**| | |**-**| | | | |

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**Date signed**

**Via Email**



**Via Post**

***Investigator signed the PICF***

| | |**-**| | |**-**| | | | |

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**Copy of the complete PICF forwarded to Participant**

***Participant Information Sheet/Informed Consent Form (PICF) was forwarded to participant:***

**Date**

| | |**-**| | |**-**| | | | |

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**Via Email**

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**Via Post**

***This form is to confirm that Participant:***

**Name**

**Date of Birth**

**Address**

***Undertook the informed consent process via telehealth/telephone on:***

**Date**

| | |**-**| | |**-**| | | | |

**By Investigator**

**(name)**

**Form for Withdrawal of Participation**

**Title**  “*Improving the self-management for people with chronic*

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 A/Prof Shilpa Jesudason

**Location** Central Northern Adelaide Renal and Transplant Service (CNARTS)

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me, or my relationship with CNARTS.

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

*In the event that the participant’s decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.*

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**Declaration by Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project 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 withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.