 

***Prince of Wales Hospitals and Sutherland Hospitals***

PARTICIPANT CONSENT INFORMATION SHEET

AND CONSENT FORM

CLINICAL TRIAL/CLINICAL RESEARCH

(EXCLUDING GENETIC TESTING AND COLLECTION/STORAGE

OF HUMAN TISSUE)

**Total Cardiac Care (TCC) Study:**

**Using a smartphone application to help patients with heart disease.**

**Invitation**

You are invited to participate in a research study into the use of a smartphone application (app) designed for people with heart disease.

The study is a collaborative study coordinated by the Prince of Wales Hospital (POWH) and the University of New South Wales (UNSW). The chief investigators are:

* Dr Sze-Yuan Ooi, Staff Cardiologist, Department of Cardiology, Prince of Wales Hospital, Randwick
* Professor Nigel Lovell, Scientia Professor & Acting Head of Graduate School of Biomedical Engineering, UNSW.

 Several other hospitals are involved in the study, including:

* Department of Cardiology, The Sutherland Hospital
* Department of Cardiology, Liverpool Hospital
* Department of Cardiology, Royal North Shore Hospital
* Department of Cardiology, Port Macquarie Base Hospital

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 is to investigate whether using the TCC app (Total Cardiac Care smartphone application) to monitor participants at home has benefit for people with heart disease.

1. **Why have I been invited to participate in this study?**

You are eligible to participate in this study because your heart condition is suitable for this app, you have a smartphone that can operate the software and you have access to the internet to transmit your results to the research team.

1. **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.

New information about the treatment being studied may become available during the course of the study. 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.

1. **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, which is a randomised trial, will be run over six months.

The app being studied here differs from the standard care of people with heart disease, which does not include the use of smartphone apps. You will still receive standard medical care, which may include medications, visits from the community nurse, the cardiac rehabilitation team and appointments with your doctors. The app will be used in addition to your normal treatment. **The app does not monitor your condition in real-time. Therefore, if you feel unwell at any stage, please contact your doctor or call 000 for an ambulance.**

‘Randomised trial’: Sometimes doctors don’t know the best way of treating patients with a particular condition so comparisons need to be made between different treatments. To do this, study participants are put into groups and given different treatments, and the results are compared to see whether one treatment is better. To ensure the groups are similar to start with, a computer allocates each study participant into a group randomly, like the flip of a coin. Neither the doctor nor the study participant can decide which treatment the participant receives.

If you agree to participate in this trial, you will then be asked to undergo the following procedures:

* Sign the consent form for the study
* You will be randomly allocated to either:
	+ 1. The TCC group, where you receive the app on your smartphone, portable blood pressure monitor, and weight scale to use at home. The app will collect information about your blood pressure, weight, and activity and these will be monitored remotely by a healthcare team
	+ OR 2. standard care group
* All patients, whether they receive the app or not, will need to:
	+ Have your height and weight measured (if not already done as part of your hospital stay).
	+ Measure your cholesterol levels in the blood (although this may have already have been done during your hospital stay).
	+ Undergo a six minute walk test, where we measure the distance you can walk along a flat surface in a six minute period.
	+ Complete a questionnaire regarding your symptoms and quality of life.
* If you are randomised to receive the app, the following will occur:
	+ We will help you download the TCC app to your phone
	+ You will be provided, free of charge, with weighing scales and a blood pressure machine
	+ We will show you how to measure your weight and blood pressure, and how to upload the readings to your phone (similar to the way you tap and go with an Opal card or your “PayPass” credit card)
	+ You will need to measure your weight and blood pressure every day.
	+ We encourage you to carry your phone when you are out to automatically track the amount of physical activity you do.
	+ The app will remind you about taking your medications, and give you messages about a heart healthy lifestyle such as eating a healthy diet and quitting smoking (if you are a smoker). You will receive one of these reminders each day.
	+ The research team will use the data collected by the app (your weight, blood pressure and activity) to monitor your condition. If abnormal results are identified, we may contact you by phone and request that you visit your GP or even attend hospital. If we are not able to contact you, we may contact your nominated health care providers directly.
	+ Your data is reviewed periodically within work hours, so if you are feeling sick or you are worried about one of your readings, you should contact your treating doctor or go to the Hospital Emergency Department and not wait for the research team to contact you.
	+ Please note we will not be providing smartphones for this study, you will need to use your own to participate.
* All patients, in both randomised groups, will be asked to return at 6 months for in-person follow-up. This will be at the hospital where you were enrolled in the study. We will measure your height, weight, and cholesterol (if not already done by your own doctor) and repeat the six minute walk test.

Cholesterol test: A sample of blood taken from a vein will be required. The amount of blood taken will be equivalent to 5 millilitres (equivalent to 1 teaspoon). It will be taken at hospital when you are enrolled in the study, and again at the six month follow-up. If your cholesterol test was already done during your hospital admission, you will only need a second test at 6 months. Similarly, if you have a cholesterol test routinely with your cardiologist or GP near the 6 month follow-up date, a further blood test will not be needed.

*Data Linkage*

In addition, the researchers would like to have access to your hospital medical record to obtain information relevant to the study. Your privacy is assured at all times during the research study.

The NSW Ministry of Health and Cancer Institute NSW use personal and health information extracted from health records to run the health system. The health information exists in a number of NSW and Commonwealth administrative datasets and are de-identified to ensure your personal privacy is protected.

You will be given the option of agreeing to the use of your health information as held in the administrative databases that have come from your health records. If you give permission to do so, UNSW, on behalf of the research team,will link your health information from the following sources:

* Public and private hospital admissions, emergency departments, ambulance services, outpatient records, and birth, marriage or death registry records held by the NSW Ministry of Health
* Cancer registries
* Medicare Benefits Scheme (MBS) records
* Pharmaceutical Benefits Scheme (PBS) records (i.e., your use of prescription medicines)

The linked health information provided to the research team will be in a form that will not identify you. Any health information used from these data sources are managed completely confidentially and are used only for the purpose of the research as described for this study. With your agreement, your health information (as drawn from your health records into the administrative datasets listed above) will be included in the linked health information.

*To participate in the study, do I have to consent to linking my health information?*

No. If you want to opt-out of the linking of your health information, there is an option to indicate this choice on the consent form by ticking the box for opt-out.

1. **How is this study being paid for?**

The study is funded by a Research Grant from the New South Wales Department of Health.

All of the money from the Research Grant is deposited into an account managed by the South East Sydney Local Health District. No money is paid directly to individual researchers.

1. **Are there risks to me in taking part in this study?**

There may be risks associated with this study that are presently unknown or unforeseeable. In spite of all reasonable precautions, you might develop medical complications from participating in this study. The known risks of this study are:

* Blood tests are a part of the study, and this carries risks of bruising, and in rare cases, damage to the blood vessel.
* Use of a smartphone application is not known to have any specific risks
	+ We advise you not to actively use your phone while driving or performing other dangerous activities
	+ If using the app for prolonged periods of time, please ensure you rest your eyes adequately to prevent eye strain
* Other risks include
	+ Falling off the scale and hurting yourself
	+ The phone could heat up and cause you some discomfort if it is being used for a prolonged period of time

For the linking of your health information there is a small risk to your privacy because personal information is used in the record linkage process. This risk is minimised by separating the processes of record linkage and data analysis. The record linkage only uses personal information such as name, date of birth, and home address. At the time of linkage a unique personal identification number will replace your personal information.

The linked health information provided to the researchers contains personal identification numbers and health information but no names, dates of birth or home addresses. All privacy measures have been put in place to ensure that the confidentiality of your personal and health information are maintained, including removal of identifying information, the use of unique study numbers and adherence to strict guidelines regarding data transfer, storage and access.

1. **What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment at this hospital. If you choose not to participate, then you will still receive exactly the same medical care as you otherwise would. You may withdraw at any time from the research project.

1. **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.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is caused by the drugs or procedures, or by the negligence of any of the parties involved in the study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies.

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.

The parties to this study agree to follow the Medicines Australia *Guidelines for Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial*. These Guidelines allow for some claims for compensation to be settled without the need for legal action to be taken. The fact that the parties have agreed to abide by these guidelines in respect of the clinical trial does not affect your rights to pursue a legal remedy in respect of any injury you may suffer as a result of participation. You can obtain a copy of these Guidelines from the Secretary of the Human Research Ethics Committee.

1. **Will I benefit from the study?**

This study aims to further medical knowledge and may improve the future treatment of cardiovascular disease, however it may not directly benefit you.

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

Using the smartphone app will use mobile phone data. We expect this to be no more than 20 MB per month, but it will depend on how frequently you use the app. If you use the app multiple times per day, which is not required for the study, you may use up to 100 MB.

Most mobile phone companies allow a lot more data to be used before you are charged excess costs. On a standard 1GB plan, using the app would be expected to use about 2% of this total amount per month.

If you are unsure about this aspect of the study, we would be happy to assist you.

If you use the app when connected to Wi-Fi, this will not affect your overall data use.

You will not be paid for participation.

*Overseas Travel*

If you travel overseas within the first 30 days of joining the study, you will not be able to participate in the trial.

If you travel overseas for longer than one month during the trial period, you will not be able to participate in the trial.

If you plan to travel overseas, please inform the research team, who will plan your involvement in the trial for the time you are overseas. This is because you will not have access to your standard healthcare providers, and also because costs of using the app overseas may be very high.

1. **What will happen to my tissue sample after it has been used?**

The blood sample/s you provide during the study will be stored in accordance with standard practice of the pathology department where it was taken. Blood will not be stored later for further testing.

1. **How will my confidentiality be protected?**

Your health care providers including your general practitioner, cardiologist, outpatient and community based members of the cardiology team (e.g. heart failure nurse, cardiac rehabilitation staff) will be informed if you are participating in this study. Only specific research staff, who may need to contact you, will have access to any information that could identify you. This is so that they can contact you if any concerns are picked up by the TCC app. Otherwise, any other information that is collected about you during this study will remain confidential and will be disclosed only with your permission, or except as required by law. Your anonymous results will be held securely on a password protected database on a secure electronic server at the University of New South Wales.

1. **What happens with the results?**

If you give us your permission by signing the consent document, we plan to discuss and publish the results in a peer reviewed medical journal, and presented in an international scientific meeting. The results will also be discussed with NSW Health, who are sponsoring the study. Your details will not be disclosed, as the results will be fully anonymous.

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.

The results will be archived for 15 years and then destroyed.

1. **What happens to my treatment when the study is finished?**

At the end of the study, you will be asked to return the blood pressure machine and weighing scales so that other participants can use them. However, if you would like to continue to use these devices after the end of the study, we can help you to purchase them. In any event, you will be able to continue to use the app for your personal use, but the collected data will no longer be monitored by research staff once the study is finished.

1. **What should I do if I want to discuss this study further before I decide?**

When you have read this information, one of the researchers based at your hospital 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 him/her. The contact details are outlined below:

**Principal Investigator, Prince of Wales Hospital**

Dr Jennifer Yu

Department of Cardiology, Prince of Wales Hospital

Level 3 Campus Centre Building

Barker St, Randwick NSW 2031

02 9382 2222

jennifer.yu@health.nsw.gov.au

**Principal Investigator, The Sutherland Hospital**

Dr Daniel Robaei

Sutherland Heart Clinic
Level 2, Sutherland Hospital
The Kingsway Miranda
(02) 9540 8555

daniel.robaei@health.nsw.gov.au

1. **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. 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 them on 02 9382 3587, or email SESLHD-RSO@health.nsw.gov.au and quote HREC 18/008.

The conduct of this study at the Prince of Wales and Sutherland hospitals has been authorised by the South Eastern Sydney Local Health District. Any person with concerns or complaints about the conduct of this study may also contact the research governance officer:

The Research Governance Officer
Prince of Wales Hospital
G71, East Wing, Edmund Blackett Building
Cnr High & Avoca Streets
Randwick NSW 2031
Phone: 02 9382 4561
Email: seslhd-rso@health.nsw.gov.au

**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.**

  

***Prince of Wales Hospitals and Sutherland Hospitals***

## CONSENT FORM

**Total Cardiac Care (TCC) Study:**

## Using a smartphone application to help patients with heart disease.

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 investigation, 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 University of New South Wales, the Prince of Wales Hospital, and the Sutherland Hospital**.**

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 Sze-Yuan Ooi on telephone 02-9382 2222, who will be happy to answer them.

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

Complaints may be directed to the Research Ethics Secretariat, South Eastern Sydney Local Health District, Prince of Wales Hospital, Randwick NSW 2031 Australia (phone 02-9382 3587, fax 02-9382 2813, email SESLHD-RSO@health.nsw.gov.au.

# Signature of participant Please PRINT name Date

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**Signature of witness Please PRINT name Date**

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# Signature of investigator Please PRINT name Date

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**Consent to linking health information**

**I consent to:**

* The linking of my personal and health information with the NSW Ministry of Health records for hospital and emergency departments, ambulance service, births, marriage or death registries
* The researchers affiliated with the study using my linked health information for the purposes of the study in a manner that does not disclose my identity.

**OR** I choose to **opt out** of the linking of my personal and health information as described in the information sheet. I understand this opt out does not impact on my participation in the other parts of the study.

# Signature of participant Please PRINT name Date

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**Signature of witness Please PRINT name Date**

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# Signature of investigator Please PRINT name Date

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***Prince of Wales Hospitals and Sutherland Hospitals***

**Total Cardiac Care (TCC) Study:**

## Using a smartphone application to help patients with heart disease.

## WITHDRAWAL OF CONSENT

I hereby 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 the University of New South Wales, the Prince of Wales Hospital, the Sutherland Hospital or my medical attendants.

# Signature of participant Please PRINT name Date

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The section for Revocation of Consent should be forwarded to:

Dr Sze-Yuan Ooi

Department of Cardiology,

Level 3, Campus Centre Building

Prince of Wales Hospital

Barker St, Randwick NSW 2031

02 9382 2222

Szeyuan.ooi@ehc.com.au