 

 **Participant Information Sheet/Consent Form**

**Interventional Study** -*Adult providing own consent*

*[Insert site]*

|  |  |
| --- | --- |
| **Title** | *TCC – COVID: A single-arm observational study of an app-based model of care for patients managed in community isolation with COVID-19 infection* |
| **Short Title** | *TCC-COVID* |
| **Protocol Number** | *1.4* |
| **Project Sponsor** | *South Eastern Sydney Local Health District* |
| **Coordinating Principal Investigator/ Principal Investigator** | *Dr. Sze-Yuan Ooi* |
| **Associate Investigator(s)** | *Dr. Kristen Overton, Prof Branko Celler, Dr Paul Hamor, Dr Jennifer Yu, Prof Nigel Lovell, Prof Guenter Schreier, Dr Praveen Indraratna, Dr Ben Kwan, Dr Pam Konecny* |
| **Location**  | *Prince of Wales, St. George and Sutherland Hospitals* |

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

**1 Introduction**

You are invited to take part in this research. This is because you have been diagnosed with COVID-19. The research involves using a smartphone application called TCC-COVID to support patients with COVID-19.

This Participant Information Sheet/Consent Form contains further information about this research. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Make a list of questions about anything that you don’t understand or want to know more about. Before deciding whether to take part, you might want to speak to a friend or your local doctor.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part.

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

• You agree to take part in the research project

• You agree to undertake the monitoring as described

• You agree 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?**

TCC-COVID is a smartphone application which allows doctors and nurses to help care for you while you are in isolation with COVID-19. Telehealth monitoring has been shown to be an effective way to remotely support patients and the TCC app has been used to successfully support patients with other health problems.

However, this is the first time this app is being used to monitor people with COVID-19. Further, this research involves using a particular pulse oximeter, a device which measures your oxygen levels and heart rate, which is not currently registered for use in Australia, This pulse oximeter is already approved for use in Europe and the USA. We are usingthis device because due to the COVID-19 situation there are no other large supplies of Australian approved devices.

**The aim of this research project is to use the TCC-COVID app and pulse oximeter to monitor and support people isolated at home with COVID-19 and to see if it is beneficial.**

This research has been initiated by a team of doctors and engineers (see names above).

This research has been funded by the South Eastern Sydney Local Health District and UNSW.

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

After you were diagnosed with COVID-19, you would have been contacted by a member of the research team by phone or video-link, to check your eligibility to take part in this research and to give you further information about this research. If you agree to participate, you must sign the consent form and send us a copy, e.g. by taking a photograph or scan of the signed pages on your phone and emailing it to us.

You will then be enrolled in the study, and the following will be involved:

1. You will be asked about your medical history and any medications you take.
2. You will receive instructions on how to download the TCC-COVID smartphone app.
3. We will deliver a pulse oximeter to you. This is a device that can measure the amount of oxygen in your blood (the oxygen saturation), as well as your heart rate. It is worn on your finger, and gives a reading after a few seconds. It is not painful or uncomfortable.

**This particular pulse oximeter is a trial device as it is not currently registered for use in Australia, even though it has passed regulatory approvals in Europe and the USA.** It has been validated by our research team in other recent trials. We are using this device because due to the COVID-19 situation there are no other large supplies of Australian approved devices.

1. Twice a day, you will use the app to enter your heart rate and oxygen saturation. This information will get sent to the research team and your treating medical team. You will receive a reminder to send these measurements at *8am* and 4*pm.*
2. Once a day, you will answer 3 questions about your symptoms. You will receive a reminder to do this at 8am daily.
3. You may send your measurements more often if you like, but we request that you please do not send us less than what is described above.
4. Your data will be reviewed centrally by the research team and your treating doctors and they may contact you to ask you further questions, or to advise you to go to hospital.
**Please note that the app does not monitor your condition in real-time: If you feel you need urgent medical attention please call 000 and inform them that you are known COVID 19 positive and require transportation to the nearest emergency department.**
5. After you have recovered from the illness, and cleared by your treating team to come out of isolation, you will be asked questions regarding your health, for feedback regarding the programme, and given instructions on how to return the pulse oximeter to us.
6. You may contacted again at a later stage by the research team to ask you for further feedback on the program.

*Your Data*

If you agree to participate, your data entered into the TCC-COVID mobile-phone application will be stored in a cloud-based secure server called “KIOLA”, which allows the research team and treating doctors to review your information. The server is located locally in Sydney, NSW. All your data will be protected by encryption methods that comply with NSW eHealth privacy and security standards.

Your other study information will be stored in a REDCap database. Only the research team will have access to this data. REDCap is a secure web application which meets the standards required to contain private personal information including health information.

By agreeing to participate, you agree to allow the research team to obtain your health data from your hospital medical record (electronic medical record, eMR), in order that we have accurate information about your medical history and medications, as well as results and hospital admissions related to your COVID-19 illness.

**All of your information will be kept confidential.**

**Please note, the TCC-COVID app does NOT track your physical location.**

*Data Linkage*

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, the Centre for Health Record Linkage and the Australian Institute of Health and Welfare, 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

• NSW Cancer Registry

• Medicare Benefits Schedule (MBS) records

• Pharmaceutical Benefits Scheme (PBS) records (i.e., your use of prescription medicines)

• National Death Index

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.

*Additional costs*

There are no fees associated with participating in this research project, nor will you be paid. The smartphone application, pulse oximeter and the medical care required as part of the research project will be provided to you free of charge. Your participation in this program will require less than 30 megabytes of data from your smartphone. 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 use about 3% of this total amount per month. If you use the app when connected to Wi-Fi, this will not affect your overall phone data use.

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

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

After you have been diagnosed with COVID-19, you are required to remain in your home till you have been both symptom free for 72 hrs AND at least 10 days after symptom onset. You will need to maintain a distance of 2 metres from anyone else in the home. ***Participating in this trial does not change this, and you should continue to adhere to the guidance provided to you by your treating team.***

Participating in this research does not involve any restrictions in regard to medications, diet or physical activity, but you must follow the self-isolation guidelines provided to you by your treating team.

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

It is anticipated that 2,000 people will participate in this trial, across three hospitals in the South Eastern Sydney Local Health District (Prince of Wales, Sutherland and St George Hospital).

The research team is made up of doctors from the three hospitals, as well as engineers from the University of New South Wales and the Austrian Institute of Technology.

**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 research at any stage, and you will be required to return your pulse oximeter.

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 your local hospital.

If you do decide to take part, you should keep a copy of this document.

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

You do not have to take part in this research project to receive care. The alternative to participating would be the current practice for home-based care. At the time of writing, this consists of phone calls approximately every two days from your treating doctor and no monitoring of your oxygen levels or heart rate. COVID-19 being a new and rapidly evolving challenge, there is no accepted “standard of care”. As more people are diagnosed with COVID-19, it may not be possible for your treating doctor to continue to call all people with the condition at the current frequency. The research team can inform you further with up-to-date information regarding current practice for home-based care.

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

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include reassurance to you that your condition is being monitored, and helping us to identify who needs to be hospitalised because of a deterioration in their condition.

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

* Use of a smartphone application is not known to have any specific risks
	+ If using the app for prolonged periods of time, please ensure you rest your eyes adequately to prevent eye strain.
* The pulse oximeter is not known to have any specific risks
* For both your phone and pulse oximeter, do not allow other individuals in the home to touch it, as there could be a risk of spreading the infection by doing this.

As with any electronic data collection, there is a risk that your confidentiality may be breached. To minimise this risk, we have implemented rigorous steps to protect your information from misuse, unauthorised access and disclosure, compliant with local and international standards for private health information.

There is a risk to your privacy associated with linking of your health data because personal information is used in the record linkage process. This risk is minimised by separating the record linkage process from the data analysis process. The record linkage uses personal information such as name, date of birth, and home address. After linkage a unique personal identification number will replace all of your personal information. The linked health information used for research will then contain personal identification numbers, but ***not***other identifying information such as 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. Your data will be stored in secure encrypted and password-protected servers which are compliant to local and international standards for private personal information including health information.

**10 Can I have other treatments during this research project?**

Whilst you are participating in this research project, you may take all of the medications or treatments you have been taking. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project.

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

If you decide to withdraw from the project, please notify a member of the research team. This notice will allow us to discuss any health risks or special requirements linked to withdrawing with you.

If you do withdraw your consent during the research project, the research team will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the team up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

You will also be given instructions for the return of the pulse oximeter.

**12 Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

• The program being shown not to be effective

• Lack of available medical staff

• Lack of availability of equipment

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

After it has been determined that you have completed the trial (approximately 14 days) you will be contacted by the research team. You will be required to return your oximeter to your local hospital’s COVID-19 clinic.

If results from the trial are published in a medical journal, the publication will made available to you.

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

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

Your information collected in the TCC-COVID app will be stored in an encrypted format in a secure, cloud-based server called “KIOLA” and will be only accessible by the research team and your COVID-19 treating team. This will include some information to help identify you, so that your treating team can contact you if required.

By signing the consent form you consent to the study doctor and 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 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 study 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, except with your permission. The results will be provided as a summary of all the participants who took part in the trial, and will not focus on individuals.

Information about your participation in this research project will be recorded in your health records.

In accordance with relevant Australian and NSW privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study 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.

**15 Complaints and compensation**

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital. You may also be eligible for compensation.

**16 Who is organising and funding the research?**

This study has been funded by the South Eastern Sydney Local Health District (NSW State Government) and the University of New South Wales.

You will not benefit financially from your involvement in this research project.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

**17 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 St. Vincent’s Hospital, Sydney.

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.

Apart from ethics approval, all studies go through a governance approval at the hospital that the research is taking place.

**18 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 problems **related to your involvement in the project** (for example, any side effects, technical app problems), you can contact the principal study doctor:

|  |  |
| --- | --- |
| Name | Dr. Sze-Yuan Ooi |
| Position | Staff Specialist |
| Telephone | (02) 9382 0700 |
| Email | szeyuan.ooi@ehc.com.au |

If you have any medical problems related to your COVID-19 infection that are **not related to this project**, you can call health direct, available 24-hours, on 1800 020 080.

**If you feel you need urgent medical attention, please call 000 and inform them that you are known COVID 19 positive and require transportation to the nearest emergency department. Please note that this app does not monitor your condition in real-time.**

Feelings of anxiety, distress and concern about COVID-19 are normal. If you need mental health support, you can speak with a trained mental health professional by calling:

Lifeline 13 11 14

Kids Helpline 1800 55 1800

Beyond Blue 1300 22 4636

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

**Complaints contact person**

|  |  |
| --- | --- |
| Name | [Name] |
| Position | *[Manager, St. Vincent’s Hospital Research Office* |
| Telephone | svhs.research@svha.org.au |
| Email | 02 8382 4960 |

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:

|  |  |
| --- | --- |
| Reviewing HREC name | St. Vincent’s Hospital |
| HREC Executive Officer | [Name] |
| Telephone | 02 8382 4960 |
| Email | SVHS.Research@svha.org.au |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Local HREC Office contact (Single Site -Research Governance Officer)**

|  |  |
| --- | --- |
| Name |  *[Insert details as per local governance]* |
| Position |  |
| Telephone |  |
| Email |  |

**Consent Form -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | *TCC – COVID: A single-arm observational study of an app-based model of care for patients managed in community isolation with COVID-19 infection* |
| **Short Title** | *TCC-COVID* |
| **Protocol Number** | *1.4* |
| **Project Sponsor** | *South Eastern Sydney Local Health District* |
| **Site Principal Investigator for [Insert site]** | *[Insert name]* |
| **Coordinating Principal Investigator** | *Dr. Sze-Yuan Ooi,*  |
| **Associate Investigator(s)** | *Prof Branko Celler, Dr Paul Hamor, Dr Jennifer Yu, Prof Nigel Lovell, Prof Guenter Schreier, Dr Praveen Indraratna* |
| **Location**  | *[Insert site]* |

**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.
* I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Prince of Wales Hospital 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 am satisfied with the answers.
* 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 copy of this document to keep.
* I understand that, if I decide to discontinue the study, I may be contacted to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

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

**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

• I consent to 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.

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

**Form for Withdrawal of Participation -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | *TCC – COVID: A single-arm observational study of an app-based model of care for patients managed in community isolation with COVID-19 infection* |
| **Short Title** | *TCC-COVID* |
| **Protocol Number** | *1.4* |
| **Project Sponsor** | *South Eastern Sydney Local Health District* |
| **Site Principal Investigator for [insert site]** | *[Insert name]* |
| **Coordinating Principal Investigator** | *Dr. Sze-Yuan Ooi*  |
| **Associate Investigator(s)** | *Prof Branko Celler, Dr Paul Hamor, Dr Jennifer Yu, Prof Nigel Lovell, Prof Guenter Schreier, Dr Praveen Indraratna* |
| **Location**  | *[Insert site]* |

**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 the Prince of Wales Hospital.

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