Department of Rehabilitation Medicine
Port Kembla Hospital
PO Box 21, Warrawong NSW 2502
Telephone: 02 42238019

Dear Participant

Re: Illawarra Covid-19 Outcome Study (ICOS)

I am a Senior Staff Specialist in the Illawarra Shoalhaven Local Health District. I am writing to you to invite you or your child to participate in our Covid-19 Outcome Study.

Being a new medical condition we do not understand how Covid-19 can affect the human body in the longer term. Reports from overseas suggest that Covid-19 may cause ongoing health issues after the initial recovery period. We do not know how long it takes for Covid-19 patients to return to full function and their pre-Covid lifestyle.

We would appreciate if you could kindly help us understand Covid-19 better by enrolling in our online/telephone study which will only take about 10 minutes to complete. All information supplied by you will be de-identified and remain fully confidential. **We would like to hear from you even if you have completely recovered.**

For further information, please scan the QR code below to read the Participant Information Sheet.

To participate, please read the consent on the back of this page and then do **one** of the following:

1. **Email** your consent to participate to: ***ISLHD-CovidResearch@health.nsw.gov.au***
2. **SMS** "I agree to participate in the ICOS Study" to: **0459 887 682**
3. **Telephone 0459 887 682** and leave a message.
4. **Write** to: Olivia Fischer, ICOS Study, Research Central, Level 8, Wollongong Hospital, NSW 2500.

Please do not hesitate to call **0459 887 682** or email us on **ISLHD-CovidResearch@health.nsw.gov.au** if you need further clarification.

Your participation in this study will help us understand how we can help Covid-19 patients in the community. Thank you very much for your assistance.

Kind regards

Stuart

Dr Stuart Tan **MBBS (NSW), FAFRM (RACP)**
Specialist Physician in Trauma & Rehabilitation

Illawarra COVID-19 Outcome Study (ICOS)

A research study to identify health issues and needs of individuals with COVID-19 over a period of 24 months

INFORMATION FOR PARTICIPANTS

We are inviting you to take part in a research study. Please read this information which will help you decide.

You have just been diagnosed with Coronavirus 2019 (COVID-19) – a new type of infection that we have very little understanding of its longer term effects on you.

1. Why are we doing this study?
The aim of this study is to understand the longer term effects of Covid-19 infection on the human body including potential complications on various organs so that we can ensure that individuals diagnosed with Covid-19 stay healthy and can return to pre infection lifestyle. The increased understanding will help us anticipate and prevent potential complications as well as allow us to advise your local health service on what services they need to provide in our community.

2. What will the study involve?
● You will be asked to provide consent to participate in this study. You will be asked to sign the consent form and send it to one of the investigators via email (scan) or photo (text message). The email address to send the consent form to is ISLHD-CovidResearch@health.nsw.gov.au and the mobile number is 0459 887 682.
● You will be asked to answer questions such as your age, sex, pre-existing illness, current medications, any new symptoms, current level of functioning and activities level at enrolment and then at 1, 3, 6, 12,18 and 24 months.
● You will be asked to complete a survey either online or by telephone (if you prefer) at enrolment, 1, 3, 6, 12,18 and 24 months. It is estimated that your time commitment for this study is 10 minutes at each of these times.
● We will ask your permission (via the consent form) to access some of the data for this study from your medical record (ISLHD), GP/specialists or other health care professionals. These are: COVID-19 test results, previous medical conditions, COVID-19 severity, chest imaging (CT/X- ray), liver function tests, blood test results, duration of hospital stay if applicable, ventilator use if applicable, any medical complications (lung/heart/kidney/liver/other).
● You may be contacted to clarify any major reported symptom(s) and to advise you to seek medical attention from your nominated health care provider(s).
●All information provided by you are strictly confidential.

3. What are the possible risks of taking part?
We do not anticipate any risks with this study as there is no intervention involved. If you experience any significant symptoms or have concerns about your recovery, please contact your nominated health care provider.

4. What are the benefits of taking part?

● You have the opportunity to discuss your health concerns if any with the clinicians on the research team.
● Your participation in this study will improve the current knowledge of how to manage Covid-19 patients on a longer term basis.
● There are no costs involved in taking part in this research, nor will you be paid.

5. What will happen to the information collected for this study?

● Your information will be kept strictly confidential. The only people who will be allowed to look at information that could identify you (such as your name) will be the investigators of this study.
● You will not be given the details of your individual research results. However, you will be informed of any information that is collected that could have an impact on your health.
● At the end of the study, a summary of the research outcomes can be made available if requested.
● Your data (de-identified, which means you cannot be identified) will be published in peer-reviewed publications and presented in scientific conferences. You data may also be put onto a public repository (which is a publically accessible database) if required to do so by a journal for publication. You will not be able to be identified in this database.
● If there are any surprising (e.g. secondary or incidental) findings that we did not anticipate, we may use this data (you will not be able to be identified) for another research project. This means we would use your data for another study but you would not be told about it.

6. Who is conducting this study?

● The study is being conducted by Dr Stuart Tan (Specialist Physician in Trauma & Rehabilitation Medicine, ISLHD, Stuart.Tan@health.nsw.gov.au), Dr Lyndel Hewitt (Research Clinician, ISLHD, Lyndel.Hewitt@health.nsw.gov.au) and Olivia Fischer (Research Assistant, ISLHD, Olivia.Fischer@health.nsw.gov.au)
● If at any time you have any questions, please do not hesitate to ask. Please contact ISLHD-CovidResearch@health.nsw.gov.au or by phoning the mobile number 0459 887 682.

7. Do I have to take part?

You are not required to take part in this study. Your decision will not affect your relationship to the investigators or with your local health service. If you do take part, you are free to withdraw at any time without giving a reason. No further information will be collected.

8. Who has reviewed this research project?

This study has been reviewed by the Health and Medical Human Research Ethics Committee of the University of Wollongong. If you have any concerns or complaints regarding the way this research has been conducted you can contact the UOW Ethics Officer on (02) 4221
3386 or email rso-ethics@uow.edu.au.

Thank you very much for your time.

Consent Form

Title: Illawarra COVID-19 Outcome Study (ICOS)
Principal Investigator: Dr Stuart Tan (stuart.tan@health.nsw.gov.au)
Investigators: Dr Lyndel Hewitt (lyndel.hewitt@health.nsw.gov.au), Olivia Fischer (olivia.fischer@health.nsw.gov.au)

This study is being conducted by the team listed above. I understand that the data collected will be used to determine the longer term clinical and functional outcomes and to identify health issues and health needs among individuals diagnosed with Covid-19.

I consent for the data to be used anonymously in that manner. I agree to the following:

Declaration by Participant

- I have read the Participant Information Sheet
- 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 relationship to the investigators or with the Local Health District
- I understand that I will be able to keep a copy of this signed document
- I give permission for the investigators of this study to obtain my results from the ISLHDCOVID-19 testing centre
- I will provide the investigators my past medical history, a list of my current medications, investigation results and information required for the purpose of the study.
- I authorise the investigators to obtain and clarify medical information required for the study from hospital records, my GP/specialists and other health care professionals.
- I understand that all information collected in this study will remain confidential and that I cannot be identified in any research and academic studies, which may be published.
- I consent for the use of my collected information in future research if secondary or incidental findings are found as long as my data remains anonymous
- I consent for my data (de-identified – you cannot be identified) to be uploaded onto a public digital repository if required to do so for publication of this research into a scientific journal
- I understand that I can withdraw my consent to participate in the research project by telling one of the study investigators.

Complaints may be directed to the joint University of Wollongong / Illawarra Shoalhaven Local Health District health & medical Human Research Ethics Committee. Phone: 02 4221 3386, Email: research-services@uow.edu.au Address: Research Services Office, Building 20, Level 1, University of Wollongong, Northfields Ave, Wollongong NSW 2522

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Signature of Participant Please PRINT name Date

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Address of Participant

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Contact number of Participant

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Signature of Investigator Please PRINT name Date