

Illawarra COVID-19 Outcome Study (ICOS)

A research study to identify health issues and needs of individuals with COVID-19 over a period of six 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. Your 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 Dr Jose Cuenca (Research Clinician, ISLHD, Jose.Cuenca@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.