

Project Title: The Burden of Long Covid in Aotearoa New Zealand: Establishing a Long COVID Registry

This Participant Information Sheet is to help you decide whether this study is something you would like to join.

It will give you an overview of:

- why we are doing this study,
- what it would involve you doing,
- the potential benefits and risks to you,
- how your information will be stored and used, and
- what happens at the end of the study.

If you have any additional questions or concerns after reading this Participant Information Sheet, please email paula.lorgelly@auckland.ac.nz.

You are welcome to discuss this study with others, such as whānau, friends or a health professional, before deciding whether to proceed.

What is the purpose of the study? Studies show that around 10–20% of people infected by COVID-19 may go on to develop long COVID. This means there may be some 200,000 individuals impacted by long COVID in Aotearoa New Zealand. With this research we will establish a long COVID registry. We hope this will help us to understand

- the burden of long COVID on patients, including learning more about symptoms,
- the impact of long COVID on quality of life,
- the different pathways and possible complications to receiving diagnosis and treatment,
- the impact of long COVID on work and caregiving,
- the cost of long COVID on individuals and our wider society,
- the distribution of this burden, and
- whether the impacts improve or worsen over time.

What is long COVID? The Ministry of Health defines long COVID as ongoing symptoms that continue 12 weeks or more after infection with COVID-19. These could be the same symptoms or new symptoms. A clinical diagnosis is not required to identify as having long COVID, you can self-identify in this study as having long COVID symptoms. Perhaps you're not sure? That's ok too, we'd still like to understand your post COVID experience. You can find out more about long COVID and its symptoms here

<https://longcovidsupport.co.nz/support/symptoms/>

What is the study design? We are using a registry-based cohort study design. We will be collecting data using survey completed by people with self-reported long COVID symptoms. The questions we are asking have been co-designed with people who have lived experience of long COVID in Aotearoa New Zealand.

Who are we? Our project team is made up of researchers from the University of Auckland | Waipapa Taumata Rau and independent contractors.

- Professor Paula Lorgelly, Principal Investigator, University of Auckland | Waipapa Taumata Rau, email: paula.lorgelly@auckland.ac.nz
- Jenene Crossan (Ngāi Tahu), Co-Investigator who has lived experience of long COVID
- Andrew McCullough, Research Assistant, University of Auckland | Waipapa Taumata Rau
- Associate Professor Daniel Exeter, Named investigator, University of Auckland | Waipapa Taumata Rau

The study is overseen by a Kaitiaki Rōpū (Advisory Group). The members of Te Rōpū Kaitiaki are:

- Witi Ashby (Ngāti Hine, Ngāti Kawa)
- Iris Pahau (Te Aupouri, Te Rarawa, Ngāti Kuri, Ngāti Awa)
- Mona Jeffreys
- Ngapera Riley (Te Arawa, Ngāti Uenukukopako, Ngāti Roroooterangi, Ngāti Whakaue, Tūhourangi)
- Marianna Churchward (Lotofaga, Faleasiu, Samoa)
- Jenene Crossan (Ngāi Tahu)
- Andrew McCullough
- Paula Lorgelly

Who can take part? We are aiming to initially recruit 3,000 New Zealand adults (aged 18+) with self-reported long COVID.

I no longer have long COVID If you have had long COVID in the past and recovered, or your long COVID symptoms are now explained by another condition we would still like to hear about your experience.

I had long COVID in the past If you have had long COVID in the past and recovered, or your long COVID symptoms are now explained by another condition we would still like to hear about your experience.

Participation and withdrawal Your participation in this research is completely voluntary and will not affect the care you receive. You do not have to give a reason for not wanting to participate. If you would like to participate, you are under no obligation to stay in the study and can withdraw your consent at any time during the study. Whether or not you decide to join us, we thank you for your time and consideration!

You can withdraw your consent by logging back into the registry and accessing the 'Withdraw My Consent' page on the registry dashboard. You may also telephone Professor

Paula Lorgelly (09 373 7599 extn 89392) and ask to withdraw from the study. This will remove your data from the registry. If we have already undertaken analysis of the data you will not be able to withdraw from that, but your future preferences will be noted and your data will not be used in future analyses.

You may change your consent for the optional components of the study (signing up for other research and future data linkages – see below) by accessing the ‘My Data Preferences’ page on the registry dashboard and changing your previous responses to these consent questions.

What is involved? You will first need to sign up using Google (you can use your Gmail), you will also have the opportunity to create a Google account if you do not already have one. Using Google to sign in does not provide Google with access to your data, it simply means your registry data are protected using a secure and encrypted authentication (login) method. You can leave the survey, come back, and log in to where you left off. This is explained on the Google Authentication page [hyperlink].

Next you will be asked to consent to take part in the registry and different elements of data collection. This is explained on the consent page.

Finally, you will be asked to fill in surveys which you can do online or by telephone (please contact us to take part by telephone). The types of questions in these surveys are related to your COVID-19 infection(s), use of health services, experience with long COVID and how long COVID has impacted your personal, social and work life. The surveys will appear on the registry dashboard within the website. We will email you reminders to complete surveys. You are free to choose which surveys you would like to complete and in what order.

At the completion of any survey (or exiting the survey if you need a rest) please remember to sign out of Google. If you do not log out of Google your previous survey responses may be accessible to the next user of the computer/device. To log out of Google click the link on the registry dashboard.

How long will it take? Each survey should take you no longer than 10 minutes in total. However, if you cannot finish a survey in one sitting, your progress is automatically saved so you can finish it another time. You will need to submit each survey in order for the research team to be able to access your responses. You will be sent an email reminder if you have started a survey but not completed it.

Are there ongoing surveys? Yes. We will send you a reminder to complete a monthly survey about your quality of life. Each month you will be asked to complete six short questions that will not take more than five minutes. Six months after you registered with the registry you will be asked to complete another survey so we can understand how your symptoms, diagnosis, work etc might have changed.

How will my data be collected? The survey uses Qualtrics. Qualtrics is a secure browser-based software for creating, distributing, and analysing surveys. The University of Auckland | Waipapa Taumata Rau has a subscription to the software. The data will be collected in

Qualtrics and then exported to a secure university server for storage.

What are the benefits of taking part? Analysis of the registry data could be used to help identify gaps in health and social services support. The information can be used to make a case for funding important services and/or implementing policies that would help people suffering from long COVID.

Are there any risks of taking part? We do not expect that participating in this study would expose you to any serious risks. It is possible that completing the surveys may affect any potential fatigue/tiredness you are experiencing because of long COVID. If this happens, please log out, rest and come back later, or seek medical help if symptoms worsen. Similarly, you might find you experience distress when completing some of the questions on your quality of life or changes in your circumstances as a result of your long COVID symptoms. If this happens, please seek medical help and you may wish to visit Long Covid Support Aotearoa <https://longcovidsupport.co.nz/> which shares the lived experiences of others with long COVID. Please note that that researchers will not review any survey responses (including those assessing mental health) until data analysis is undertaken.

Will any costs I incur be reimbursed? Costs related to participating in this research, such as internet/mobile data charges or telephone tolls will not be reimbursed. If you do not have ready access to the internet, please contact us so we can complete a telephone interview with you.

Where can I learn more about findings from the study? We will regularly update the Long Covid Support Aotearoa website with our latest research findings <https://longcovidsupport.co.nz/>. The findings from this study (not including any identifiable individual information) will be reported to the Ministry of Health and will also be used in academic publications, presented at conferences in the community. Findings from the study may also receive media coverage. We will send out an annual e-newsletter prepared for participants which will provide information on our findings.

How do you ensure my confidentiality? We take our participants' confidentiality very seriously. It is necessary to record your name and email address so that we can (a) send you follow up surveys, (b) advertise long COVID research projects to you should you consent to this and (c) link your data to other databases should you consent to this. We will never give out your name or contact details. Only Professor Paula Lorgelly and trusted researchers working in a secure environment at the University of Auckland | Waipapa Taumata Rau will have access to your identifiable information. Your contact details will be stored in an encrypted database and kept separate from all your other responses. Your survey responses will be converted to numbers in an encrypted data file, and these data will be stored indefinitely for research purposes but will at no time be stored with your name or contact details. We will use an electronic, de-identified encrypted copy of your survey data for our analyses.

How will my data be used in future research? Studies seeking to understand or treat long COVID may wish to recruit participants through the long COVID registry. Researchers would need to submit a request to the research team for the

characteristics/background/demographics of individuals they want, along with the details of their study. Te Rōpū Kaitiaki (our advisory group) will review these requests to ensure they align with the aims of the registry and are mana enhancing. Professor Paula Lorgelly and the research team will identify those individuals who meet the criteria of interest, confirm the individuals have consented to being contacted for other studies (that are not related to this registry study of burden) and the registry research team will contact those participants to tell them about the study. No registry data will be released without participant consent.

What are the benefits of using my data in future research? Your data could help researchers to understand who is impacted but long COVID and why. It could also help researchers to understand if there are different types of long COVID and allow them to investigate which treatments might work and for whom.

Are there any risks to my data with future research? Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

What does data-linking mean and involve? In this research we would like to link your study information with other data sets which include information about you. This is called 'data-linking'. Data-linking in this study is optional, you can consent to data-linking on the consent form. In this study we will link the registry data to Stats NZ's Integrated Data Infrastructure (IDI) – a large research database containing de-identified microdata about people and households, including data on health, education and training, housing, income and work, benefits and social services, and census information. We will link this using your NHI number (if you provide it) or your name, date of birth and sex.

What are the benefits of data-linking? Data-linking can produce a detailed picture of individuals. It will allow for analyses to be undertaken beyond the follow-up period of the study. Researchers will be able to investigate the burden of long COVID without having to request any more information from you. Data-linking with the Stats NZ's IDI also means researchers (including iwi) can undertake comparisons of individuals with long COVID to those without, thereby understanding the additional impact of long COVID on healthcare use, employment, social support.

Are there any risks with data-linking? Data-linking increases the risk of identifying individuals and possibly others who may be in the same households, organisations, iwi or hapū. Some of the data sets being linked may have been designed, and some data may have been collected, without the intention of them being used with other data sets. Some data sets may have been collected in ways which have resulted in biases, meaning that there is the potential for inappropriate inferences to be drawn. These things have the potential to cause harm. While we have taken steps to minimise their likelihood, we cannot guarantee they will not occur.

How are you ensuring tino rangatiratanga? Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori people. We recognise the taonga of the data collected for this study. To help protect this taonga and honouring the rights of Māori as an Indigenous community and treaty partners to exercise rangatiratanga over taonga Māori:

- We have worked in partnership with our Kaitiaki Rōpū about the collection, ownership, and use of study data.
- We will allow Māori organisations to access de-identified study data, for uses that may benefit Māori.
- We will be guided by the Tāngata Whenua members of our Kaitiaki Rōpū with respect to interpreting our findings and disseminating our research outputs.

What about tikanga and data-linking? Ngā Tikanga Paihere is a framework and tool used by Stats NZ that:

- guides safe, responsible, and culturally appropriate use of data,
- ensures data use is carefully considered, and
- ensures data practices occur in good faith.

The framework was designed to guide the appropriate use of microdata in the Stats NZ IDI, with a focus on how data about Māori and other under-represented sub-groups are used for research purposes. We will be using Ngā Tikanga Paihere to guide on how we can bring better insights to the registry and linked data, by building relationships with communities from whom the data originates.

Who is funding this study? The Long COVID Registry Aotearoa New Zealand has received funding from the Ministry of Health via the COVID-19 and National Immunisation Programme Research Programme and the EuroQol Foundation.

Who has approved this study? This study has been approved by an independent group of people called the Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Northern B HDEC has approved this study.

Any other questions? For help relating to the registry, there is a help and FAQ section within the registry website.

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Prof Paula Lorgelly, Principal Investigator
09 373 7599 extn 89392
paula.lorgelly@auckland.ac.nz

If you want to talk to someone who is not involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)

Email: advocacy@advocacy.org.nz
Website: <https://www.advocacy.org.nz/>

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHIC
Email: hdecs@health.govt.nz

More information about long COVID-19
<https://covid19.govt.nz/testing-and-isolation/if-you-have-covid-19/long-covid>

For whānau haua | people with a disability
<https://www.imaginebetter.co.nz/>

For Māori
<https://www.karawhiau.nz/news-and-stories/making-sense-of-long-covid/>

For Pacific peoples
<https://www.positivelypacific.org.nz/>

**APPROVED BY THE NORTHERN B HEALTH AND DISABILITY ETHICS
COMMITTEE ON 7 JUNE 2023, REFERENCE NUMBER: 2023 EXP 15097.**