

Locality: Wellington

Lead Investigator: Sue Huang

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What information is included in this participant information sheet?

This sheet is to give you information to help you decide whether you want to take part as an adult participant of the WellKiwis Influenza study (i.e. WellKiwis Adult). It includes the reason why we are doing the study, what we are asking you to do, the risks and benefits of the study, and what happens when the study is finished. Please read this sheet carefully and discuss with your family, whānau, friends, or healthcare providers before deciding whether to continue with the study or not. It is entirely up to you to decide if you want to stay in the study for another year. You can stop taking part in the study at any time – no reason needs to be given. Stopping your participation in the study will not affect your current or future health care.

What is the WellKiwis Adult study?

The WellKiwis Adult study aims to understand the adult immunity or protection against influenza (flu) through infection or vaccination. Findings of WellKiwis will help the New Zealand government make choices about flu vaccine recommendations and make decisions about how to reduce the impact of flu infection in the community. The study will also provide information that can be used to improve flu vaccines in the future and better prepare for pandemics.

What are we asking you to do in this study?

Study activities during 2022 will be similar to last year. You will be asked to do the following activities:

1. Enrolment

Consent: We will send you a study invitation message/letter with a link to an online consent form. If you decide to stay in the study, you will need to complete the consent form. If you have difficulties to open the online consent form, you can go to <http://wellkiwis.co.nz/> to find a consent form to print out, sign and return electronically (details are on the consent form). If you want a hard copy consent form, you can call us on 0800 493555 (08004WELLKIWI), or email us at WellKiwis@esr.cri.nz, and we will mail it to you with a pre-paid envelope included.

Enrolment questionnaire: After you complete the online consent, you will be automatically directed to the enrolment questionnaire to update those details including contact information, vaccination and health and influenza-like illness (ILI) status. The questionnaire will take less than 10 minutes to complete. If you have not done this in a few days, we will remind you by email/text or phone including a link to the questionnaire.

2. Follow-up during the flu season (usually April-September)

Weekly surveys: We will send you weekly email/text messages to ask whether you had a flu/COVID-19 vaccine, and if you have been sick with cough, fever or other respiratory symptoms.

Post-vaccine blood: If you report to us that you had a flu/COVID-19 vaccine, a blood sample will be collected 3-6 weeks after the vaccination.

- We will email/text/call you about how to have your samples collected at Awanui Labs (formerly WSCL) collection rooms. You can also get information by visiting <https://www.wellkiwis.co.nz/providing-blood-samples/>
- A phlebotomist (a person trained to collect blood) will take a blood from you. We may ask for a further sample in cases initial samples are not sufficient for testing.
- The volume of blood for an adult is about 15 mL (a tablespoon)
- You are welcome to perform a karakia at any sample collection.

Nose swab: If you report to us that you have a flu-like illness, such as cough and fever and your symptoms meet our illness case definition, a respiratory swab is needed. If you are willing to collect a nose swab by yourself, we will send you a collection kit with step-by-step instructions and a video link for viewing. We will also instruct you how to get a courier to come to collect the swab and transport it to the WHO National Influenza Centre in Upper Hutt. On arrival, we will test your swab for flu and other respiratory viruses including the SARS-CoV-2 virus that causes COVID-19. If the swab shows no flu/SARS-COV-2 virus then we will let you know, and there is nothing that needs to be done further.

Post-flu/COVID-19 blood: If your swab is tested positive for the flu/SARS-COV-2 virus, we will work with you to collect a pair of blood samples from you. The first blood will be taken 1-2 weeks after illness onset and another 4-7 weeks later.

Study updates: We will keep you informed about the study on a regular basis. In case of any COVID-19 community transmission or lockdowns during your time with us, we will provide you with study updates to make sure that you and your family are kept safe.

3. Follow-up after the flu season (usually October-March)

Annual blood: We will collect a once only annual blood sample for each participant. It will be used as a post-season blood for the current year and pre-season (i.e. baseline) blood for the following year.

Annual questionnaire: We will carry out one annual questionnaire during the off-season, to get any updates on your contact details, health and conditions associated with getting flu as well as your feedback on the study.

Study updates: We will keep you informed about the study on a regular basis.

Thank you voucher: You will receive a \$30 gift card after each blood or swab sample to recognize your time and effort.

What are the benefits of taking part in this study for me? You will find out if you were ill from the flu, SARS-CoV-2 or another respiratory virus during the winter. The study can help you to find ways to reduce the impact of illness due to the infection. The study will contribute to knowledge about the immune responses against flu virus and the virus spread. This will inform measures to better prepare us for and to respond to future pandemics.

Who is involved in running the WellKiwis Influenza study?

The Institute of Environmental Science and Research (ESR) is the leading agency for the WellKiwis Influenza study. The adult component of the WellKiwis Influenza study is also called SHIVERS-II (the second iteration of the Southern Hemisphere Influenza and Vaccine Effectiveness Research and Surveillance programme). SHIVERS is a long series of research on the influenza virus and vaccine.

Here are some other important details of the WellKiwis Influenza study:

- The WellKiwis Influenza study is a part of a large international collaboration funded by the United States National Institutes of Health (US NIH) through the St. Jude Children's Research Hospital in Memphis.
- WellKiwis is multi-agency collaboration including your general practice (GP), Compass and Te Awakairangi Health Network and others in Wellington, ESR, the Universities of Auckland and Otago, Regional Public Health, the Capital Coast and Hutt Valley District Health Boards, the Malaghan Institute and St. Jude Children's Research Hospital.
- The New Zealand Health & Disability Ethics Committee has approved WellKiwis (2021 AM 0952 10/01/2022).
- This study is observational clinical research. **No medications or interventions are tested in this study.**
- Study staff will provide you with public health advice to support you to lessen the impact of the flu/COVID-19 infection.
- For your personal clinical care and management, please discuss with your own doctor.

What testing is done on my samples? And where?

Blood samples and swabs will be sent to ESR's National Influenza Centre at Wallaceville, Upper Hutt.

- Swabs will be tested for flu and other respiratory viruses (SARS-CoV-2, respiratory syncytial virus, rhinovirus, enterovirus, parainfluenza virus types 1-3, adenovirus and human metapneumovirus).
- Blood samples will be tested for antibodies, other immune cells, and specific genes that associate with immune responses. Some of these immune tests will be done at Wallaceville and at the Malaghan Institute of Medical Research in Wellington. A small amount of your samples will be sent to St. Jude Children's Research Hospital in Memphis for more complex testing that cannot be performed here. None of these tests being done would be important for your healthcare.
- Your samples may be tested to help in the response to public health issues, such as understanding the body's immune response to a new influenza virus or other pandemic viral threats and the samples used for these purposes will be de-identified.
- Your samples will be stored securely for 10 years after the study ends, and then will be disposed of safely.
- You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whānau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose.

How is my privacy protected? What happens to the information you provide?

Your test results and information are confidential:

- Your GP will receive the results done on your swab which may show if a virus has caused your flu-like symptoms. Swab results will be sent to your GP about two weeks after the swab is taken.

- If your sample is tested positive for COVID-19, your result is required to be reported to the Medical Officer of Health as COVID-19 is a notifiable disease in NZ.
- Your GP will not receive the results done on your blood samples as these results are not for clinical purposes. The blood tests need to use samples across a number of years, and therefore the results may not be available for several years.
- Your samples will be labelled with a unique study number without any identifiable information when sent overseas, so that you cannot be identified.
- We need to use your personal information (name, date of birth and contact details) to get in touch with you and to ensure that your GP can provide you with results from the tests being done in the study. In addition to study researchers having access to this information, only the study funder and their agents, the ethics committees that approved the study, and regulatory agencies could access study records for the sole purpose of checking the accuracy of the recorded information.
- Study communications will mainly be electronic (email, text messages, and online surveys), and the study cannot guarantee the security of electronic responses to study communications.
- You have the right to ask for your personal study information and to ask for that information to be corrected, if you find an error.
- If you decide to withdraw from the study, we may process the information collected up to the point when you withdraw.
- The study staff will request information from NZ health registries, practice medical records to validate or complete missing information on your vaccination and respiratory illness/conditions and non-health related information such as demographics. Additionally, we may check your workplace influenza/COVID-19 vaccination records to validate or complete missing influenza/COVID-19 vaccination information.
- This study will comply with not only all New Zealand laws governing ethical research, but also the Privacy Act 2020.
- This study has a Certificate of Confidentiality from the United States National Institutes of Health (US NIH) to protect your privacy in the following ways. The researchers can use this Certificate to legally refuse to give information that may identify you in any US federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use this Certificate to resist any demands for information that would identify you, except for reporting of notifiable diseases to the New Zealand Ministry of Health.
- You can also contact us to get the overall study results. It may be many years before these results are available.
- Study results will be grouped together on all participants without any of your personal information to be provide to health authorities, publish them in medical journals, and make them available on the WellKiwis website (<http://wellkiwis.co.nz/>). Information collected for the study on participants will be posted on the study funder website (US NIH). **No personal identifiable information will be published.**
- All study records are confidential. They will be stored securely at ESR and will be destroyed 10 years after the study ends.

What if something goes wrong?

There are very few risks associated with this study. Taking swabs and blood samples are common and safe procedures. Nose swabs may cause brief pain, itchy nose, eye watering, or sneezing. We minimize risks by providing you with clear instructions and a video tutorial on how to take a nose swab yourself. The risk from blood collection is usually minor, such as redness or bruising around the site where the blood is taken. The procedure may also cause infection and some discomfort. We minimize risks by having trained staff take your blood samples.

If you were injured in this study, which is unlikely, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study will not affect your coverage.

Who can I talk to about this study?

- If you any questions about the study, you can contact Dr. Sue Huang and WellKiwis study staff at 0800 493555 (08004WELLKIWI) or email WellKiwis@esr.cri.nz.
- If you want to talk to someone who isn't involved with the study, you can contact a Health and Disability Advocate. Freephone 0800 555 050.

We thank you for your time and consideration of taking part in this important population health study.