WellKiwis
influenza study

Participant Information Sheet for the WellKiwis Adult Study

Locality: Wellington **Lead Investigator:** Sue Huang **Phone:** 04 529 0600

What information is included in this participant information sheet?

This sheet is to give you information to help you decide whether you want to continue 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 continue in the study for another two years. 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?

We will send you a study invitation message/letter. If you are interested in continuing with the study and consent to enrol in the study, you will need to complete an online consent form. We will send you an email or text with a link to the online consent form. The link also includes a study invitation letter and the participant information sheet.

If you have difficulties with this link, you can contact the WellKiwis team on 0800 493 555 and/or email (wellkiwis@esr.cri.nz) and we will help sort it out. Alternatively, you can go to wellkiwis.co.nz/ to download and print the consent form, sign and return it to us either electronically or by post. You can also call or email us and we will post the consent form to you with a pre-paid envelope included. If at any time you have any questions about continuing in the study, you can contact the WellKiwis study team.

Once you have consented, you will participate in the following yearly study activities (surveys, swab and blood samples), the same as in 2023 and 2024:

Surveys: Each year, we will contact you at various intervals to request information from you:

- **Weekly surveys in flu season (usually April-September):** Once the flu season starts (usually April), we will send you a weekly link to an electronic survey to ask if you received a flu shot or show any signs of a respiratory illness, such as cough and fever. If your symptoms are likely due to the flu, our study staff will call you to discuss these symptoms and may ask you to take a nasal swab to test for flu and other respiratory viruses. We will not usually ask you to swab more than once in a two-week period.
- **Annual surveys:** We will send you three surveys outside the flu season; one to check your contact details are still correct, one to ask about general health conditions associated with getting flu or respiratory illness over the last 12 months, and one to ask for anonymous feedback on your experience as a study participant.

  In addition to asking you for information via the surveys, we will provide you with study updates/newsletters as appropriate during the year.

Nasal Swab Sample Collection: If you report respiratory symptoms that are likely due to the flu, our study staff may call you and ask you to take a nasal swab by yourself (very similar to a COVID-19 RAT swab). Full instructions are provided, and our study staff can you guide you through the process if required. Swabbing involves the following steps:

- ***Pre-delivered swab collection kit***: we will arrange for the delivery of a self-swab kit to your home before the flu season starts. The kit will include the items required to take the swab, a specimen request form with step-by-step instructions, packaging for returning the swab, and a QR code linked to an instructional video on the WellKiwis website.
- ***Collecting the swab***: when you are ready, collect the swab as per the instructions provided. If you need guidance, one of our study nurses can guide you through the process over the phone.
- ***Returning the swab***: Once you have taken the swab, package it according to the instructions, then leave it in the agreed place for collection. We will arrange for the safe pick up and transport of your swab to the ESR laboratory for testing.
- ***Testing the swab***: ESR lab staff will test your swab for flu, SARS-CoV-2 and other respiratory viruses including respiratory syncytial virus (RSV), rhinovirus, human metapneumovirus, parainfluenza types 1 – 3, adenovirus and enterovirus.
- ***Reporting of test results***: Influenza and SARS-CoV-2 results are usually available within 72 hours. Results for other respiratory viruses may take up to two weeks. Once all results are available, these will be sent to you by email. Swab results are also sent to your GP and can be accessed through the Manage My Health patient portal.
- ***Positive test result for influenza or SARS-CoV-2:*** If your swab is positive for flu or SARS-CoV-2, a study nurse will contact you via phone call or text. If the swab shows that you have the flu virus, we'll work with you to arrange to collect blood samples from you.

- **Blood Sample Collection:** During the study, we will need to collect a blood sample from you a few times each year. A trained healthcare professional experienced in taking blood will collect these samples.
  - The collection schedule is:
    - ***Baseline blood:*** You do not need to provide this sample because we have already collected your 2024 season annual blood sample. This will be used as a post-season blood for the previous year and pre-season (i.e. baseline) blood for the current year.
    - ***Post-vaccine blood:*** if you have a flu vaccination, a blood sample will be collected 4-7 weeks after the vaccination.
    - ***Post-flu blood:*** a pair of blood samples will be collected from you if the respiratory swab is positive for the flu virus. The first blood will be taken 1-2 weeks after illness onset and another 4-7 weeks later.
    - ***Annual blood:*** collected post the flu season, usually during October-December each year.
  - We will email/text/call you about how to have your samples collected at Awanui Labs' collection rooms. You can also get information by visiting our study website (http://wellkiwis.co.nz/).
  - 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.

- **Thank you e-gift card:** You will receive a $30 e-gift card after each blood or swab sample to recognise your time and effort, and to help with any study-related costs (such as phone calls and texts).

This study is observational clinical research. No medications or interventions are tested in this study. For your personal clinical care and management, please refer to your doctor.

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 nurses will provide you with public health advice to help you to lessen the impact of illness due to the infection.

In addition, 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, Te Whatu Ora Health NZ National Public Health Service, the Malaghan Institute and St. Jude Children's Research Hospital.
- The New Zealand Northern A Health & Disability Ethics Committee has approved WellKiwis under Reference 2024 AM0952.
- The Lead Investigator for the WellKiwis Study based in Wellington, NZ is Dr. Sue Huang.

What testing is done on my samples? And where?

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

- Nasal 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/or 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. You and your GP will not receive the results done on your blood samples because these blood test results are not for clinical purposes and the blood tests need to compare samples collected across a number of years. You can contact us to get the overall WellKiwis results.
- 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?
During this study, the study researchers, clinical team and laboratory team will record enrolment information about you and your participation in the study. This includes your responses to surveys, and details you provide in discussions with the WellKiwis team, such as your symptoms during the winter surveillance. If needed, information from your GP and hospital records may also be collected. You cannot take part in this study if you do not consent to the collection of this information.

Identifiable Information
Identifiable information is any data that could identify you (e.g. name, date of birth, or address). The following groups may have access to your identifiable information:

- WellKiwis study and clinical team staff who will contact you about your participation in the study. Your name, address and phone number will be used by couriers to arrange delivery and collection of self-swab kits.
- New Zealand based laboratory staff, who will process and report your specimen results.
- Your GP will be notified of your specimen (swab) results, or if a study test gives an unexpected result that could be important for your health or wellbeing. This allows appropriate follow-up to be arranged.
- 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.
- Study monitors, to make sure the study is being run properly and that the data collected is accurate.
- The sponsor's representatives, ethics committees, or government agencies from New Zealand or overseas for the purpose of audit. Audits are done to make sure that participants are protected, the study is run properly, and the data collected is correct.

De-identified (Coded) Information
To make sure your personal information and specimens are kept confidential, information that identifies you will not be included in any report generated by the WellKiwis team AND/OR any study information or specimens sent to the sponsor. Instead, you will be identified by a unique study code. The WellKiwis team will keep a list linking your unique code with your name, so that they can be identified by their coded data if needed. This list will be kept strictly within the WellKiwis team and will not be sent overseas.

The following groups may have access to your coded information and specimens, which may be sent and stored overseas:

- The sponsor and its representatives, for the purposes of this study.
- Organizations working with or for the sponsor, for the purposes of this study.
- Regulatory or governmental authorities for legal and regulatory duties such as public health surveillance and pandemic response.

Anonymised Information
The data from this study will be put together for analysis. Results on all study participants will be grouped together in anonymised way to be provided to health authorities, published in medical journals, presented in scientific conferences, and made available on ESR and study websites (www.esr.cri.nz, www.wellkiwis.co.nz).
No personal identifiable information will be published.
The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you. You can also contact us to get the overall study results. It may be many years before these results are available.

Data Linking
In this study we will be linking your study information with other data sets (such as vaccination registries and general practice medical records) which include information about you. This is called 'data-linking'. Data-linking in this study is required to validate or complete missing information on your vaccination and respiratory illness/conditions and non-health related information such as demographics.

- 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.

Data storage and duration

- Your electronic data will be stored in password-protected databases. Physical data is stored in filing cabinets at one of ESR's secure sites, in a restricted access building.
- Your data will be retained for at least 10 years after the study ends, and then will be disposed of safely.

Your test results and information are confidential:

- 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.

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.

Study communications will mainly be electronic (email, text/SMS message, and online surveys), and the study cannot guarantee the security of electronic responses to study communications.

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.

Your coded and linked information will be sent overseas. Other countries may have lower levels of data protection than New Zealand. There may be no New Zealand representation on overseas organisations which make decisions about the use of your information.

Rights to Access Your Information.

- You have the right to request access to your information held by the research team and to ask for that information to be corrected if you find an error.
- If you have any questions about the collection and use of information about you, please ask the WellKiwis study team.

Rights to Withdraw Your Information.

- You may withdraw your consent for the collection and use of your information at any time, by informing the WellKiwis study team.
- If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

- Information collected up until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

Who can I talk to about this study?

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

Dr. Sue Huang, Principal Investigator
Phone: 0800 493 555
wellkiwis@esr.cri.nz

If you want to talk to someone who isn't 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:

Email: hdecs@health.govt.nz
Phone: 0800 400 569 (Ministry of Health general enquiries)

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

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WellKiwis Influenza Study Locality: Wellington, New Zealand (NZ)
WellKiwis Influenza Study Lead Investigator: Dr. Sue Huang
Ethics Committee Reference: The NZ Northern A Health and Disability Ethics Committee has approved WellKiwis under Reference 2024 AM 0952.