

Frequently asked questions for the **WellKiwis** household study



WellKiwis
influenza study

ESR AND STUDY NAMES

Who is ESR?

ESR stands for the Institute of Environmental Science and Research. ESR is New Zealand's Crown Research Institute that specialises in science relating to people and communities. ESR is the leading agency for the WellKiwis Influenza study.

What does **WellKiwis** stand for?

Well refers to Wellington. **Kiwis** refers to New Zealanders.

WellKiwis can also refer to the wellbeing of New Zealanders in the study.

What does **SHIVERS** stand for?

SHIVERS stands for Southern Hemisphere Influenza and Vaccine Effectiveness Research and Surveillance

SHIVERS is a long series of research on influenza virus infection and vaccination.

What is the relationship between **WellKiwis** and **SHIVERS**?

The WellKiwis study is a member of the SHIVERS project family:

- The WellKiwis adult study is the second iteration of SHIVERS (SHIVERS-II)
- The WellKiwis infant study is the third iteration of SHIVERS (SHIVERS-III)
- The WellKiwis household study is the fourth iteration of SHIVERS (SHIVERS-IV)

Locality: Wellington region

Lead investigator: Sue Huang

Phone: 04 529 0600

What is the National Influenza Centre?

The National Influenza Centre is part of ESR and is located in Upper Hutt.

The National Influenza Centre employs scientists and public health researchers who work on influenza and other respiratory viruses, including COVID-19.

What is influenza?

Influenza (also called flu) is a serious illness that affects millions of people globally. A virus called influenza causes it.

In New Zealand, young children, older adults and people with underlying medical conditions are particularly vulnerable to its infection.

What is COVID-19?

COVID-19 is an infectious Coronavirus disease which can affect your lungs and airways. It was first identified in December 2019 in Wuhan, China. COVID-19 has since spread globally, including New Zealand

A virus called Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) causes COVID-19.

STUDY PURPOSE AND FUNDER

Briefly, what is the WellKiwis household study?

The WellKiwis Household study involves families, with at least one child aged 19 or younger, living in Wellington City, Hutt Valley, and Porirua to take part in this study.

The study will follow these families for up to seven years. The aim is to see how a person's prior exposure to the flu virus (or vaccine) influences their on-going immune responses to subsequent flu exposures over time. It will also help us to know how the flu virus spreads from an infected person to others in a household setting.

Why is this study being done?

The study will provide information to contribute to make more effective and longer lasting flu vaccines for New Zealand and the world in the future.

Who is doing the study?

This is a multi-agency collaboration led by ESR.

Other collaborating organisations include your general practice, Te Awakairangi Health Network, the Universities of Otago and Auckland, Te Whatu Ora, Capital, Coast, Hutt Valley and Wairarapa, Wellington SCL, the Malaghan Institute and St. Jude Children's Research Hospital.

Who is funding the study?

The study is a part of a large international collaboration and is being funded by the United States National Institutes of Health (US NIH) through the St. Jude Children's Research Hospital.

Has the WellKiwis household study obtained ethics approval?

Yes, New Zealand's Health and Disability Ethics Committee approved the study (NTX11.11.102.AM58)

PARTICIPANT ROLE/RIGHTS

What happens if I agree to participate?

Once you and your family members consent to take part in the study:

- We will monitor you and your participating family members up to seven years.
- You will receive regular surveys to inform us if you have received flu vaccine or if you have cough, fever or other respiratory symptoms throughout the flu season (usually April-September).
- If you are ill, we may ask you to take a nose swab to test for flu or other respiratory viruses. If the swab tests POSITIVE for the flu virus, we will take two small blood samples from you.
- When the first member of your household (either you or someone else) tests positive for the flu, we will check on everyone in the family to see if the flu virus spreads from the first person to other family members. We will monitor everyone's symptoms and ask you all to take a nose swab every 3rd day until two consecutive negative flu results for the family are returned. We will also collect two small blood samples from all family members, one after the first positive flu result, and one 4-7 weeks later.
- If you have a flu vaccination, we will also take a small blood sample.
- We will take one annual blood sample from you every year.

Do I have to take any medication for the study?

No medications or interventions will be given at any point of the study.

Do I have to do all the study activities?

No, you can decline any study activities at any time.

You are always free to leave the study at any time without any reason.

What happens if I change my mind and don't want to be in the study?

You can withdraw from the study at any time without any reason. This will not affect you or your family's healthcare.

The research team will remove your name from the study records. We may process the information and samples collected up to the point when you withdraw.

Will I get paid to take part in this study?

To recognise the costs of study activities (email/text messages) and your time and effort, you will receive an e-gift card worth \$30 after each sample collection.

Who do I talk to if I have questions during the study?

You can call Dr. Sue Huang or ESR study staff at 0800 493555 (08004WELLKIWI), or email the research team at Wellkiwis@esr.cri.nz

If you have concerns about the study, you can contact the New Zealand Health and Disabilities Advocate at Freephone 0800 555 050.

What is the benefit of taking part in this study?

- You will find out if you and your household members are infected with the flu virus or another respiratory virus.
- You will find out how the flu virus spreads within your household and will receive public health advice to reduce the impact of the infection.
- You will contribute to scientific knowledge about the body's immune responses to the flu.
- You will contribute to the development of a more effective and longer lasting flu vaccine.
- You will help New Zealand and the world to better prepare for and respond to pandemics/epidemics.

INFORMATION COLLECTION AND CONFIDENTIALITY

What kind of information is being collected?

After you consent to take part in the study, you will be asked to participate in various study activities where different information is collected:

- **Enrolment survey:** a designated household representative will provide physical address details and information on household conditions. In addition, each consented household member (or their guardian) will respond to an individual survey, including individual contact details, vaccination and health information.
- **Weekly surveys:** during the flu season (usually April-September) we will collect information from you on influenza vaccination status, and to monitor if you have been sick with influenza-like illness (ILI).
- **Regular surveys or updates:** we will keep you informed about the study on a regular basis during the year. This may involve checking your contact details are correct and asking other questions as appropriate.
- **Annual survey:** We will carry out one annual questionnaire during the off-season, to get any updates on your contact details, health conditions associated with getting flu, as well as your feedback on the study.

How is my information stored?

Information gathered through this study is stored electronically and securely. The researchers use computer networks which are password protected and only accessible to people involved in the project. Paper copies of some information may sometimes be used. These are stored securely in a locked cabinet and periodically sent for archiving at a secure storage facility.

Can I check my study information?

Yes, you can email Wellkiwis@esr.cri.nz or contact the study Principal Investigator (Sue Huang at 04-529-0600) or study staff at 0800 493555 (08004WELLKIWI) to check your study information and ask for that information to be corrected if you find an error.

Will my information be sent overseas?

Yes. Some of the samples will be sent to St. Jude Children's Research Hospital in Memphis, USA for more complex testing that cannot be performed here in NZ. Your study data will have a unique study number assigned to it.

This means that when your study data is sent to St. Jude Children's Research Hospital in Memphis, it contains no identifiable information, and the overseas researchers will not be able to identify you.

Who will have access to my study information?

The study staff will use your personal information you provided to contact you. In addition to study staff having access to this information, only the ethics committee that approved the study or any relevant regulatory authority or their approved representative could access study records for the sole purpose of checking the accuracy of the recorded information.

BLOOD SAMPLES

What are blood samples tested for?

Blood samples will be tested for antibodies and other immune cells, and specific genes associated with immune responses. These tests will show if you have developed immunity to the flu/COVID-19 virus or vaccine.

How many blood samples will be collected from me?

- One annual blood sample each year.
- Additional blood samples only:
 - if you get a flu vaccination
 - if you test positive for the flu
 - if you never provided a baseline blood sample when you joined the study
 - if your first family member (either you or someone else) tests positive for the flu.

How much blood will be taken?

We will take a small sample amount, depending on the participant's age:

- Less than 4 mL (less than a teaspoon) of blood from infants under 6 months old
- 4 mL from those 6 months to 2 years old
- 8 mL (less than a tablespoon) from those aged 2–5 years and over
- 15 mL (one tablespoon) from those aged over 5 years.

When do I have the blood samples collected?

We will remind you when it is time to do so, if needed.

1. The Annual blood sample is collected at the end of the flu season, usually between October and December.
2. The post-flu vaccine blood sample is collected after you have had the flu vaccine. We will contact you to arrange this.
3. When the first family member tests positive for flu, we will contact you to collect a pair of samples. The first around one week after the positive result, the second around 4-7 weeks later.

Where do I go to have the blood test done?

Our clinical study staff (phlebotomists/nurses) will visit you at a convenient place/time to do the blood collection for you.

They may also guide you to visit one of the participating SCL blood collection rooms for blood collection if this is a better option for you.

Who will take the blood sample?

Healthcare professionals (study clinical staff or SCL staff) who are experienced in taking blood will collect blood samples from you.

Do I need to make an appointment for blood sample collection?

If a blood sample is required from you/your household, the WellKiwis clinical team will contact you to arrange a convenient date and time. If you choose to go to a participating SCL collection centre, an appointment is not required as they operate on a queue system.

Is it OK to say a blessing at the blood collection?

Yes, you are welcome to say a blessing (karakia) during any blood collection.

Where does the blood go after the sample has been taken?

The blood will go to the National Influenza Centre (NIC) at ESR in Upper Hutt for sample processing and some testing. Then a small amount of these samples will be sent to the St. Jude Children's Research Hospital (SJCRS) (Memphis, USA).

Why do I need to give blood more than once?

We need to compare immune cells during the first, second and any further exposures to the flu infection or vaccination. These changes in immunity cells provide insights on how the body responds to the flu infection or vaccination.

Are the samples only being used for this study or can they be used for other studies?

The samples will only be used for this study. In the case of an epidemic or pandemic such as COVID-19, the samples may be used to help us to take actions to try to lessen the impact of the pandemic on the community. The samples will not contain any identifiable information.

Why do the samples have to be stored for 10 years after the study ends, or 10 years after my child turns 16 years?

Research studies are required to keep samples for this amount of time as some tests may need to be rechecked or clarified.

Research Ethics Committees also require that samples are kept for this long.

How are the samples disposed of?

Samples will be destroyed at the end of the storage period using normal laboratory procedures. Laboratory staff will heat the blood samples at a very high temperature (autoclave) to destroy them.

Will I be able to get my blood returned to me after the research testing is completed?

No, it will not be possible to have the blood returned to you because the blood sample will be processed to look for specific components (antibody, T cells and B cells etc). In most cases, all the sample will be used.

Is it a risky procedure when a blood sample is collected?

Taking blood samples is a common and safe procedure. The risks from blood collection are usually minor, such as redness or bruising around the site where the blood is taken.

The procedure could cause infection and some discomfort. We minimise these risks by having a trained and experienced phlebotomist (person to take the blood) and experienced nurses take your samples.

NOSE SWAB

How are swabs taken?

Swabs will usually be taken either by yourself, or by the guardian/caregiver of younger participants (self-swabbing).

We will deliver a swab kit to your home, including step-by-step instructions and a self-swab training video so that you can see exactly how to do it. Nurses can also guide you through taking a self-swab. Once a self-swab has been taken, nurses will arrange for the swab to be transported to the ESR laboratory.

What help will I get to take a self-swab?

We will provide you with written instructions, a training video to watch and nurses may also guide you while you are taking the swab.

How many swabs will be taken?

It depends on the swab test result:

- If the first ILI swab is negative for any flu virus, no more swabs will be taken.
- If the first ILI swab is positive for flu virus, a swab is needed every 3rd day for each participating family member in the household until there are two consecutive negative flu results.

Is it OK to say a blessing at a respiratory swab collection?

Yes, you are welcome to say a blessing (karakia) during any respiratory swab collection.

Is it a risky procedure when a nose swab is collected?

Taking swabs are common and safe procedures with very few risks:

- Nose swabbing may cause brief pain, itchy nose, eye watering, or sneezing.

Where does my swab go?

Your nose swab will be sent to the National Influenza Centre at ESR. The laboratory is in Wallaceville, Upper Hutt.

What is the swab tested for?

The laboratory staff will test the swab for the flu and other respiratory viruses (SARS-CoV-2, respiratory syncytial virus, rhinovirus, enterovirus, parainfluenza virus types 1-3, adenovirus and human metapneumovirus).

REPORTING OF RESULTS AND PRIVACY

How do I know my test results?

- Clinical and study staff will let you know the test results for flu within 72 hours after sample receipt.

- Your GP will receive the results done on your respiratory swab, about two weeks after ESR receives the swab.
- You can also request the result through study staff.
- Your GP will not receive information about your blood sample. This is because these blood samples are not for clinical purposes.

How is my privacy protected?

Study results on all participants will be grouped together without any of your personal information provided to health authorities, published in medical journals, and made 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.

Can I be identified through my blood samples or respiratory swabs?

Your blood samples and respiratory swabs will be tagged with a unique reference number rather than your name. Only authorised members of the research team can link this reference number to your name.

What will happen to the study results?

Results will be grouped together and summarised in a study report.

This report will be shared with New Zealand health professionals and public health agencies. Results will be also presented at health conferences and published in medical journals. ESR's WellKiwis website will include links to these documents.

No individuals will be identifiable in these study results.



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Te Whatu Ora
Health New Zealand



This study is being conducted at the Institute of Environmental Science and Research (ESR) at 66 Ward Street, Upper Hutt with New Zealand ethics approval (NTX11.11.102.AM58). It is a multi-agency collaboration including participating general practices in Wellington, ESR, Te Awakairangi Health Network, participating general practices, Te Whatu Ora, Capital, Coast, Hutt Valley and Wairarapa, Wellington SCL, the Universities of Otago and Auckland, Malaghan Institute of Medical Research and St. Jude Children's Research Hospital (SJCRH). It is a part of a large international collaboration funded by United States National Institutes of Health through SJCRH in Memphis USA.