

# 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 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 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 virus 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 a Coronavirus disease is an infectious 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?

We are looking for 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 7 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 includes your general practice, Te Awakairangi Health Network, the Universities of Otago and Auckland, the Hutt Valley and Capital and Coast District Health Boards, Regional Public Health, 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/COVID-19 vaccine or if you have cough, fever or other respiratory symptoms or throughout the flu season (usually April-September).
- If you are ill, we may take a nose or throat swab to test for flu or other respiratory viruses. If the swab tests POSITIVE for the flu/COVID-19 virus, we will take two small blood samples from you.
- When the first family member (either you or someone else) tests positive for the flu/COVID-19, we will check on everyone in the family to see if the flu/COVID-19 virus spreads from the first person to other family members. We will monitor everyone's symptoms and take a nose or throat swab every 3rd day till two consecutive negative flu/COVID-19 results for the family as well as a pair of small blood samples.
- If you have a flu/COVID-19 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.

Why does the WellKiwis influenza study include investigation of COVID-19? Influenza virus infection can cause influenza-like illness (ILI) with symptoms such as cough and fever. These symptoms are similar to symptoms caused by SARS-CoV-2 virus and other respiratory viruses.

The only way to tell which virus is causing these respiratory symptoms is to run a laboratory test.

This is one of the main reasons that the WellKiwis household study includes investigation of COVID-19 and other respiratory viruses because we need to understand the cause of respiratory illness among our study participants. It is also an opportunity to understand the behaviour of the virus.

### 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 member's healthcare.

The research team will remove your name from the study records. Depending on your wish, we may or may not process the information and samples 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), your time and effort, you will receive an e-gift card worth \$30 after each sample collection or visit.

## 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 on Wellkiwis@esr.cri.nz

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

What is the benefit of taking part in this study?

- Finding out if you are infected with the flu/COVID-19 or another respiratory virus.
- Finding out how the flu/COVID-19 spread among your household and provide public health advice to reduce the impact of the infection.
- Adding to the scientific knowledge about the body's immune responses to the flu/COVID-19.
- Contributing to the development of a more effective and longer lasting flu/COVID-19 vaccine.
- Help New Zealand and the world to better prepare for and respond to pandemics/epidemics.

## INFORMATION COLLECTION AND CONFIDENTIALITY

### What kind of my information is being collected?

Soon after you consent to take part in the study, we will send you a few surveys to collect your information:

- Enrolment survey: a designated household representative will provide physical address and household conditions. In addition, each consented household member (or their guardian) will respond to their individual survey, including individual contact details, vaccination and health information.
- Weekly surveys during the flu in-season (usually April-September): collect information on influenza/COVID-19 vaccination status, and influenza-like illness (ILI).
- Regular surveys or updates on a monthly or bimonthly or quarterly basis during flu off-season (usually October-March): provide study update, collect participant feedback and update their contact details.
- Annual survey: collect updated contact details and clinical updates (ILI, vaccination, general health, underlying conditions), and participant feedback on the study including logistics.

### 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 (8004WELLKIWI) to check your study information and ask for that information to be corrected if you find an error.

## Will my information be sent overseas?

Your study data will have a unique study number and contains no identifiable information. This means that when this information is sent to St. Jude Children's Research Hospital in Memphis, 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 tests will be done?

- One annual blood test each year.
- Additional blood tests only:
  - if you get a flu/COVID-19 vaccination
  - if you have a flu/COVID-19 infection
  - If you have never provided any once only baseline blood sample
  - If your first family member (either you or someone else) is positive for the flu/COVID-19.

### 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 test done?

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

### Where do I go to have the blood test done?

Our clinical study staff (phlebotomists/nurses) will visit you wherever is the most convenient place to do the blood collection for you.

They may also guide you to visit one of SCL blood collection rooms for blood collection.

### 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 tests?

You do NOT need to make an appointment. A time and place will be arranged with you.

## How long will it take to have the blood taken?

It will take just a few minutes.

## 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/COVID-19 infection or vaccination. These changes in immunity cells provide insights on how the body responds to the flu/COVID-19 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, so you cannot be identified.

## 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?

If any of the blood sample is not used up beforehand, it 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). Most of time, the sample will be used up after testing completion.

## 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 OR THROAT SWAB

### How are swabs being taken?

Swabs will be taken either by nurses (nurse-swabbing) or by oneself (self-swabbing):

- **Nurse-swabbing:** Nurses will continue to take swabs in a situation where self-swabbing is not feasible. Nurses will also take swabs during a validation trial by running nurse-swabbing and self-swabbing in parallel to be sure self-swabbing is a valid method in our study.
- **Self-swabbing:** Nurses will introduce and train a participant to collect a nose and/or throat swab from oneself if you would like to do so.

For this, 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 will also guide you through taking a self-swab. Nurses will arrange for the swab to be transported to the ESR laboratory. We will fully implement self-swabbing once this method is validated.

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

We will provide you with written instructions, a training video to watch and nurses will 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 or SARS-CoV-2 virus, no more swabs will be taken.
- If the first ILI swab is positive for flu and/or SARS-CoV-2 virus, a swab is needed every 3rd day for each participating family member until there are two consecutive negative flu/SARS-CoV-2 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 or throat 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.
- Throat swabbing could cause some discomfort, coughing or gagging.

### Where does my swab go?

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

### What do they test the swab for?

The laboratory staff will test the swab for the flu and SARS-CoV-2 and other respiratory viruses that can cause respiratory illnesses like colds and sore throats.

## REPORTING OF THE RESULTS AND PRIVACY

### How do I know my test results?

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

- Regional Public Health will be notified of any positive COVID-19 testing because COVID-19 is a notifiable disease.
- 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 the results done on your blood sample. This is because these blood test results are not for clinical purposes and the blood tests need to use samples across a number of years, and therefore the results may not be available for several years.

## How is my privacy protected?

When we publish the results of the study, we will group the results from participants together so that none of your personal information can be identified (anonymised). Only researchers working on the project will analyse the results from the study.

## 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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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, Regional Public Health, the Capital Coast and Hutt Valley District Health Boards, the Universities of Otago and Auckland, Malaghan Institute of Medical Research and St. Jude Children's Research Hospital (SJCRRH). It is a part of a large international collaboration funded by United States National Institutes of Health through SJCRRH in Memphis USA.