



WellKiwis
influenza study

WellKiwis influenza cohort study frequently asked questions (FAQs)

Who is ESR?

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 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 stands for?

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

What is the relationship between WellKiwis and SHIVERS-III?

The WellKiwis study is a member of the SHIVERS project family. SHIVERS is a long series of research on influenza (virus and vaccine) and the WellKiwis study is the third in its series (SHIVERS-III).

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.

STUDY PURPOSE AND FUNDER

Briefly, what is WellKiwis about?

WellKiwis is a study about influenza (flu) immunity in children. The study is to follow newborns over multiple years to see how a child's first encounter to the flu virus or vaccine influences their immune responses to subsequent exposures to flu as the child grows.

Why is this study being done?

The purpose of the WellKiwis study is to 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?

Your Lead Maternity Carer (LMC) is working on this study with ESR. LMCs can be your midwife or obstetrician.

Other organisations collaborating in WellKiwis are listed on the patient information sheet. They include the Universities of Otago and Auckland, the Hutt Valley and Capital and Coast District Health Boards, Regional Public Health and other LMCs.

Is WellKiwis part of an international study?

Yes, WellKiwis is part of a large international study on influenza immunity in children. There are two other sites, one is Los Angeles, USA and another in Managua, Nicaragua.

St Jude Children's Research Hospital in Memphis is leading the international study with other collaborators at Universities and Medical Schools such as Mt Sinai, Chicago, Washington, Emory, Rochester and Stanford and Michigan.

Who is funding the study? WellKiwis is being funded by the United States National Institutes of Health (US NIH) through the St Jude Children's Research Hospital.

Has the WellKiwis study obtained the ethics approval? Yes, New Zealand's Health and Disability Ethics Committee approved the study (NTX11.11.102.AM42)

PARTICIPANT ROLE/RIGHTS

What happens if I agree to participate?

- We will monitor your child's flu-like illness for up to seven years.
- You report to us through regular surveys.
- If your child is ill, we will take a nose or throat 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 your child. A healthcare professional trained in taking blood samples will do this.
- If your child has any annual flu vaccinations, we will also take a small blood sample after the vaccination.
- Over the course of the study, we will take a ONCE ONLY baseline umbilical cord blood sample from you at the birth of your child.
- We will take one blood sample from your child every year.
- A gift card will be provided at each visit or blood collection to thank you for your time and effort.

Do I have to do all the study activities? No, you can say no to any study activity 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 child'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.

Do I have to take any medication for the study? No medications or interventions will be done in this study.

Will I get paid to take part in this study? To cover the costs of study activities (email/text messages), your time and effort, you will receive a gift card worth \$30 after each blood 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 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 your child is infected with the flu or another respiratory virus.
- Adding to the scientific knowledge about the body's immune responses to the flu in early childhood.
- Contributing to the development of a more effective and longer lasting flu vaccine.

BLOOD SAMPLES

<i>What are blood samples tested for?</i>	Blood samples will be tested for antibodies and other immune cells, and specific genes associated with immune responses. These tests will show if your child has developed immunity to the flu virus or vaccine.
<i>How many blood tests will be done?</i>	<ul style="list-style-type: none">• For you: Once only blood test for the umbilical cord blood.• For your child: one annual blood test each year. We will ask your child to do an additional blood test only if your child gets a flu vaccination and/or your child has a flu virus infection.
<i>When do I have the blood test done?</i>	For the first blood test (cord blood), we will take it immediately after your child's birth. For the other blood tests, we will remind you when it is time to do so, if needed.
<i>Where do I go to have the blood test done?</i>	Study nurses will visit you wherever is the most convenient place to do the blood collection for you or your child.
<i>Who will take the blood sample?</i>	Healthcare professionals who are experienced in taking blood from children will visit you to do the blood collection.
<i>Do I need to make an appointment for blood tests?</i>	You do NOT need to make an appointment. A time and place will be arranged with you.
<i>How long will it take to have the blood taken?</i>	It will take just a few minutes.
<i>Is it OK to say a blessing at the blood collection?</i>	Yes, you are welcome to say a blessing (karakia) during any blood collection.
<i>How much blood will be taken?</i>	We will take only a small sample amount, depending on your child's age: <ul style="list-style-type: none">• 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 years and over.
<i>Where does the blood go after the sample has been taken?</i>	The blood will go to the National Influenza Centre (NIC) at ESR in Upper Hutt for sample processing. Then these samples will be sent to the St. Jude Children's Research Hospital (SJCRC) Memphis, USA). This is the main testing centre for samples from all three study country sites. Some samples may be sent to other collaborators at Universities and Medical Schools such as Mt Sinai, Chicago, Washington, Emory, Rochester and Stanford for some specific immunology testing that cannot be done at SJCRC.
<i>Why do I need to give blood more than once?</i>	We need to compare immune cells during the first, second and any further exposures to the flu virus or the flu vaccine. These changes in immunity cells provide insights on how the body responds to the flu virus or vaccine.
<i>Are the samples only being used for this study or can they be used for other studies?</i>	The samples will only be used for the WellKiwis study. If you agree, we will use your samples to help answer questions in the case of a flu epidemic or pandemic. This will help us to take actions to try to lessen the impact of flu on the community in such an event.
<i>Why do the samples have to be stored for 10 years after the study ends, or 10 years after my child turns 16 years?</i>	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.
<i>How are the samples disposed of?</i>	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 to a very high temperature (autoclave) to destroy them.
<i>Is it a risky procedure when a blood sample is collected?</i>	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) take your child's samples.

NOSE OR THROAT SWAB

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.

Where does my child's swab go?

Your child's nose or throat swab will be sent to the National Influenza Centre at ESR. The laboratory is based in Upper Hutt.

What do they test the swab for?

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

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.

REPORTING OF RESULTS AND CONFIDENTIALITY

How do I know my child's test results?

- Your GP will receive the results done on your child's 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 child's 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.

Will my and my child's information be sent overseas?

Your child's study data will have a unique study number and contains no identifiable information. This will be sent to the University of Michigan which will put the data from all three study sites together for analysis. This means overseas researchers will not be able to identify your child.

How is my and my child's privacy protected?

When we report the results of the study, we will group participants' results together so that none of you or your child's personal information can be identified (anonymised). Only authorised researchers working on the project will analyse the results from the study.

How do I know I can't 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 also be presented at health conferences and published in medical journals. The ESR WellKiwis and SHIVERS website will include links to these documents.

No individuals will be identifiable in these study results.

How is my information stored?

Information gathered through WellKiwis is stored electronically and securely. WellKiwis researchers use computer networks which are password protected and only accessible to the WellKiwis researchers 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.

The only other individuals who have access to this information aside from the WellKiwis researchers would be the ethics committees that approved the study, and governmental regulatory agencies that make sure that studies are being conducted correctly.

Can I check my study information?

Yes, you can email Wellkiwis@esr.cri.nz or contact the study principal investigator Sue Huang or study staff at 0800 493555 (08004WELLKIWI) to check your study information.

