

What is the WellKiwis influenza study?



WellKiwis influenza study

Influenza, unlike a common cold, is a serious illness affecting hundreds and thousands of people globally and in New Zealand, particularly young children and the elderly.

WellKiwis is a study 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 flu exposures as the child grows. The purpose of the WellKiwis study is to provide information to make more effective and longer lasting flu vaccines for our populations in the future.



As the parent of a potential infant or child participant in this study, this information is to help you decide about entering you and your child in the study. It includes the reasons why we are doing the study, what we are asking you and your child to do, any risks and benefits of the study, and what happens when the study is finished.

Before deciding whether or not to join the study, please read this information and the enclosed consent form carefully and discuss it with your family, whānau, friends, and/or healthcare providers. It is entirely up to your family to decide about participating in this study. You can stop at any time – no reason needs to be given. Stopping the study will not affect any current or future health care for your child.

This is an observational study. No medications or interventions will be tested in this study.

How you and your child can help us in this study

We would like to recruit 600 Wellington mother-infant pairs (200 pairs a year for three years starting October 2019) and follow these children until 2026. The following activities are how the study plans to operate each year:

INITIAL INTERVIEW(S): If you are interested in this study, one of our study staff will contact you to arrange an interview anytime during your pregnancy and within two months after birth. If you consent to enrol yourself and your child in the study, we will ask a set of questions. These will include you and your child's contact details, your pregnancy, birth of your child, baby's height and weight and feeding, you and your child's general health, flu vaccinations and any flu-like illness and conditions associated with getting flu. If the initial interview occurs before birth, we will schedule another one after birth.

REGULAR EMAIL OR TEXT MESSAGES: Soon after the study starts, we will begin sending emails or text messages to see if your child has received a flu shot or shows any signs of a respiratory illness, such as cough and fever. These messages will be weekly during the flu seasons (usually May-September) and monthly outside of the season (usually October-April).

ANNUAL SURVEY: We will carry out one annual survey outside the flu season, to get any updates on your contact details, your child's height and weight, information on breastfeeding/nutrition, or any conditions associated with getting flu.



NOSE OR THROAT SWAB: If your child has symptoms that are likely due to the flu, our study staff will set up a time to take a nose and/or throat swab to test for flu and other respiratory viruses during the flu season. If the swab shows no flu virus then we'll let you know, and there is nothing that needs to be done further. If the swab shows that your child has the flu virus, we'll work with you to collect a blood sample from your child.

BLOOD SAMPLES: Over the study, we will need to collect a blood sample from your child a few times each year.

THE BLOOD COLLECTION SCHEDULE IS:

- **Baseline blood:** it will be collected from the umbilical cord after you give birth.
- **Post-vaccine blood:** if your child has a flu vaccination, a blood sample will be collected 3-6 weeks after the vaccination.
- **Post-flu blood:** a pair of blood samples will be collected from your child if the respiratory swab is positive for the flu virus. The first blood sample will be taken 1-2 weeks after illness onset and another 3-6 weeks later.
- **Annual blood:** collected outside of the flu season.
- **A trained healthcare professional experienced in taking blood from children will collect blood samples.**
- Less than 4 mL (less than a teaspoon) of blood will be taken from infants under 6 months old, 4 mL from those 6 months to 2 years old, and 8 mL (less than a tablespoon) from those aged 2 years and over.
- Blood collections will be timed to fit with your schedule.
- You are welcome to perform a karakia at sample collections.



What are the benefits of taking part in this study for my family?

- Finding out if your child was 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.

A gift card will be provided at each blood collection or visit to thank you and recognise your time, effort, and study-related costs.

Who is involved in running the WellKiwis study?

The Institute of Environmental Science and Research (ESR) is the leading agency for the WellKiwis study. It is a member of SHIVERS (Southern Hemisphere Influenza and Vaccine Effectiveness Research and Surveillance) 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).

The WellKiwis study is a part of a large international collaboration on influenza immunity in children:

- WellKiwis is being funded by the United States National Institutes of Health (US NIH) through the St. Jude Children's Research Hospital (SJCRH) in Memphis, USA.
- WellKiwis has sister sites in Los Angeles, USA and Managua, Nicaragua.
- In New Zealand, WellKiwis is a multi-agency collaboration including your Lead Maternity Carer (LMC), other LMCs in Wellington, ESR, the Universities of Auckland and Otago, Capital Coast and Hutt Valley District Health Boards and other collaborators of the infant cohort study.
- The NZ Health and Disability Ethics Committee has approved WellKiwis (NTX11.11.102.AM42).

What testing is done on my child's samples? And where?

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

- Nose or throat swabs will be tested for flu and other respiratory viruses that may cause symptoms in your child. The testing will be done at ESR.
- Blood samples will be tested for antibodies and other immune cells, and specific genes that associate with immune responses. These tests will show if your child has developed immunity against the flu virus or vaccine. Blood samples will be sent to SJCRH as the main testing centre for samples from all three study 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 SJCRS.

- Your child's samples may be tested to help in the response to public health issues, such as understanding the body's response to a new influenza virus.
- Study samples will be stored securely for 10 years after the study ends or 10 years after your child turns 16 years of age and will then 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 the privacy of my family protected? What happens to the information provided?

Your child's test results and information are confidential:

- 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 of your child's blood sample. It 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.
- Your child's blood samples will be labelled with a unique study number without any identifiable information when sent overseas, so your child cannot be identified by overseas researchers.
- Your child's study data with a unique study number without any identifiable information will be sent to the University of Michigan. There the data from all three study sites will be put together for analysis. This means that overseas researchers will not be able to identify your child.
- The WellKiwis study staff will use you and your child's personal information (name, NHI, date of birth, and contact details) 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.
- Study communications will mainly be electronic (email, text/SMS message, and online surveys). The study cannot guarantee the security of electronic responses to study communications.
- You have the right to check 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 WellKiwis study staff will request information from NZ health registries and practice medical records to validate or complete missing information on you or your child's vaccination and respiratory illness/conditions and non-health related information such as demographics.
- You can contact us to get the overall WellKiwis results. It may be many years before these results are available.
- Results on all study participants will be grouped together to be provided to health authorities, published in medical journals, presented in scientific conferences, and made available on the SHIVERS website (www.shivers.org.nz). 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 or 10 years after your child turns 16 years.

Can anything go wrong?

There are very few risks in this study. Taking swabs and blood samples are common and safe procedures.

- Nose swabbing may cause brief pain, itchy nose, eye watering, or sneezing.
- Throat swabbing could cause some discomfort, coughing or gagging.
- 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 minimise these risks by having a trained and experienced healthcare professional to take your child's samples.

In the unlikely event your child is injured in this study, you would be eligible to apply for ACC compensation just as you would be for an accident. 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 child's 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?

You are welcome to contact **Dr. Sue Huang** or other study staff at freephone **0800 493555** (08004WELLKIWI) with questions about this study.

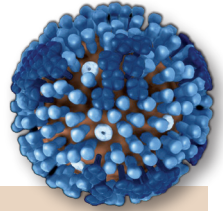
We thank you for your time and consideration of taking part in this important population health study.

WELLKIWI INFLUENZA STUDY LOCALITY:

Wellington, New Zealand (NZ) – 2019-2026

WELLKIWI INFLUENZA STUDY LEAD INVESTIGATOR:

Dr. Sue Huang, Phone: 04 529 0600



The annual burden of flu in New Zealand



UP TO
1,629,858



PEOPLE GET
INFECTED
WITH **FLU**

UP TO
391,166



PEOPLE GET
SICK WITH
MILD FLU

UP TO
20,469



PEOPLE
VISITED **GPs** WITH
MODERATE FLU

UP TO
6,519



PEOPLE
HOSPITALISED
WITH **SEVERE**
FLU

UP TO
95



PEOPLE ADMITTED
TO **ICU** WITH
SEVERE FLU

UP TO
70



DIE AS A
RESULT
OF THE **FLU**

Pregnant women with influenza are over THREE times more likely to be admitted to hospital than women who are not pregnant



The Institute of Environmental Science and Research (ESR), one of New Zealand's Crown Research Institutes, is leading the study with New Zealand ethics approval (NTX11.11.102.AM42). It is a multi-agency collaboration including Lead Maternity Carer (LMC), the Universities of Otago and Auckland, the Capital Coast and Hutt Valley District Health Boards. It is a part of a large international collaboration on the infant immunity against flu funded by United States National Institutes of Health through the St. Jude Children's Research Hospital (SJCRC) in Memphis USA.



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