

Participant information for **WellKiwis** Infant 2 study



WellKiwis
influenza study

What is the **WellKiwis** Infant 2 Study?

The **WellKiwis** Infant study is part of an international study on influenza immunity in children. It will follow babies 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 they grow. The purpose of the study is to provide information to make more effective and longer lasting flu vaccines for our future populations.

We would like to recruit an **additional 200 mother-infant pairs in the Wellington region, starting from October 2024**, to join our existing participants. The study will follow your child for up to seven years.

As the mother of a potential infant participant in this study, this information is to help you decide about joining 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.

What are we asking you and your child to do in this study?

If you register your interest in this study, one of our study staff will contact you. They will discuss the study with you, including the reasons why we are doing the study, what we are asking you and your child to do, and any risks and benefits of the study. You can ask us any questions related to the study. If you consent to enrol you and your child 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. 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.

Once you have consented, you and your child will participate in the following yearly study activities (surveys, swab and blood samples):

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

Enrolment survey: Once you consent to take part in the study, you will fill in an enrolment survey during your pregnancy and/or within 6 months after the birth of your child. We will ask you 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 enrolment survey occurs before birth, we will schedule another one after birth.



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 your child has received a flu shot or shows any signs of a respiratory illness, such as cough and fever. If your child has symptoms that 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 from your child to test for flu and other respiratory viruses. We will not usually ask you to swab your child more than once in a two-week period.

Annual surveys: We will send you an 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 general health conditions associated with getting flu or respiratory illness over the last 12 months.

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



NASAL SWAB SAMPLE COLLECTION: If you report your child has symptoms that are likely due to the flu, our study staff may call you and ask you to take a nasal swab from your child (very similar to a COVID-19 RAT swab). Full instructions are provided, and our study staff can 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 from your child 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 child's swab to the ESR laboratory for testing.

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WellKiwis infant study: Yearly study activities

Enrolment

Infant and participant questionnaires

Baseline blood sample for those who have never provided one



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Influenza season

April May June July August September

Weekly online surveys on influenza vaccination. If you report your baby receiving a flu vaccine, our clinical team will collect a post-vaccine blood sample 3 – 6 weeks after the vaccination.

Weekly online surveys on **influenza-like illness (ILI)**

If you report an ILI for your baby, our clinical team will assess your baby's symptoms and may contact you to ask you to take a nose swab from your baby.

If your baby's swab is POSITIVE for influenza (flu):

Our clinical team will contact you, usually within 48 hours, with the positive flu result. If the result is negative for flu, this will be reported via email within 1 – 2 weeks.

Our clinical team will arrange to collect two blood samples from your baby:

- one sample within 1 – 2 weeks following the positive result
- one sample 4 – 7 weeks after

Reporting swab results for non-flu viruses:

Our clinical team will contact you, usually within 48 hours, if the swab is positive for SARS-CoV-2. Results for other viruses (eg. RSV, Rhinovirus) will be available after 1 – 2 weeks:

- By email
- Via your baby's 'Manage my Health' portal
- or from your GP

Influenza off-season

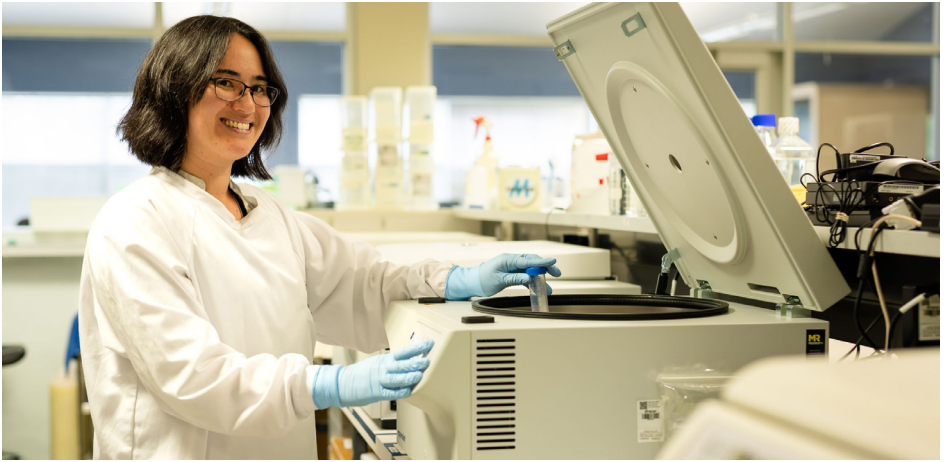
October November December January February March

Annual blood sample collection*

*We will contact you to arrange a convenient time to visit you at home to collect this sample.

Annual survey and study updates

The ILI surveillance for the year stops as the flu season has come to an end.
During this time, we do not send the weekly ILI surveys or collect swabs. This will resume the following year.
If you are concerned about your child's health during this period, please consult your GP or call Healthline on 0800 611 116.



Testing the swab: ESR lab staff will test your child's 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 child's 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 your child has the flu virus, we'll work with you to arrange to collect blood samples from your child.

BLOOD SAMPLE COLLECTION: During the study, we will need to collect a blood sample from your child a few times each year. A trained healthcare professional experienced in taking blood from children will collect these samples. The collection schedule is:

Baseline blood: This will be collected from your child at an appropriate time after you and your child consent to take part in the study.

Post-vaccine blood: If your child has a flu vaccination, a blood will be collected 4–7 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 will be taken 1–2 weeks after illness onset and another 4–7 weeks later.

ANNUAL BLOOD: This will be collected outside of the flu season.

Blood collections will usually be done in the comfort of your own home and will be arranged during working hours, at a time convenient to you and your child's schedule.

The volume of blood collected from children is small. 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.

You are welcome to perform a karakia at sample collections.



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 child's personal clinical care and management, please refer to your child's doctor.

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.
- Study nurses will provide you with public health advice in the event of your child being unwell.

In addition, you will be adding to the scientific knowledge about the body's immune responses to the flu in early childhood and how the virus spreads. This will inform measures in New Zealand, and globally, to better prepare us for and to respond to pandemics/epidemics, and will help to develop effective vaccines against these viruses.





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 the 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 called Dissection of Influenza Vaccination and Infection for Childhood Immunity (DIVINCI).
- **WellKiwis** is 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 Northern A Health and Disability Ethics Committee has approved **WellKiwis** under Reference 2024 AM 0952.
- The Lead Investigator for the **WellKiwis** Study based in Wellington, NZ is Dr. Sue Huang.

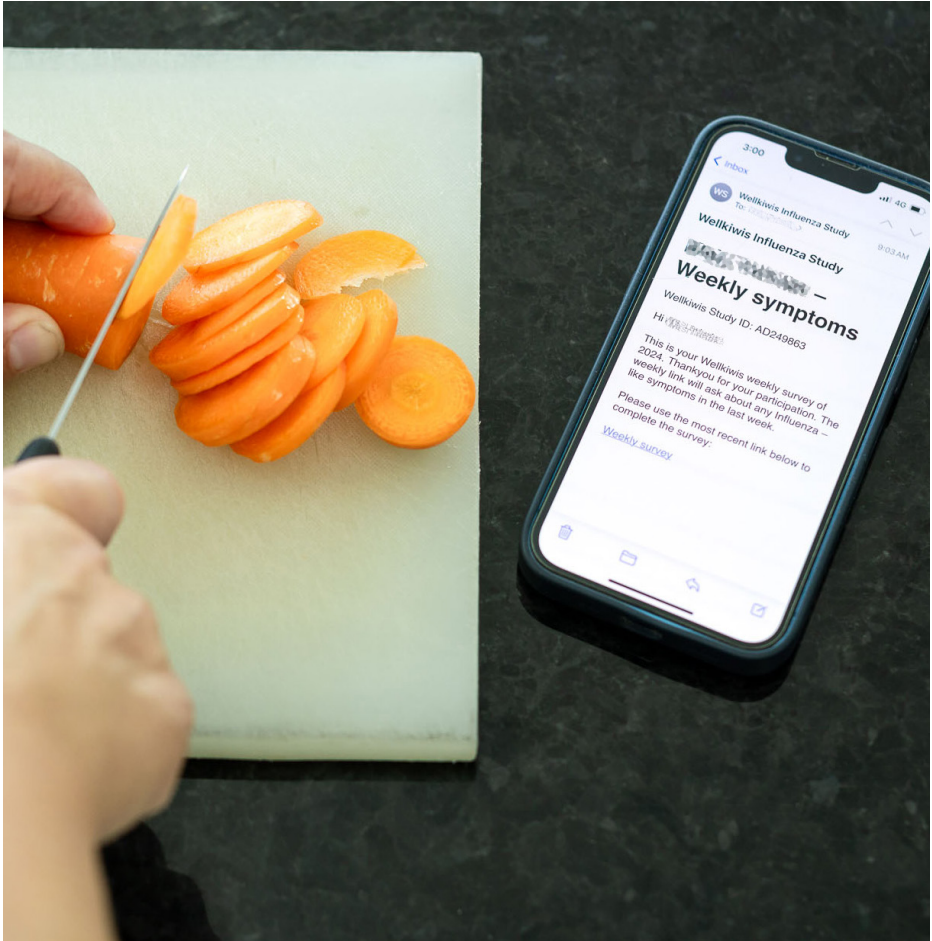
What testing is done on my child's samples? And where?

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

- Nasal swabs will be tested for flu and other respiratory viruses that may cause symptoms in your child. The testing will be done at ESR and results will be notified to you and your child's GP. The GP will receive the swab results about two weeks after ESR receives the swab.
- 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. You and your GP will not receive the results from your child's blood samples because these blood test results are not for clinical purposes and the blood tests compare samples collected across a number of years. You can contact us to get the overall **WellKiwis** results, however it may be many years before these results are available.
- Blood samples will be sent to SJCRH as the main testing centre for samples from all three DIVINCI study sites. Some samples may be sent to other collaborators at Universities and Medical Schools such as Mt Sinai, Chicago, Washington, Emory, Rochester, Melbourne and Stanford for some specific immunology testing that cannot be done at SJCRH.
- Your child's samples may be tested to help answer questions about influenza and/or other respiratory viruses, if required for public health action, such as in the case of an epidemic or pandemic.
- 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.



What happens to my information?

During this study, the study researchers, clinical team and laboratory team will record enrolment information about you and your child, and your child's participation in the study. This includes your responses to surveys, and details you provide in discussions with the **WellKiwis** team about your child, such as their symptoms during the winter surveillance. If needed, information from your child's GP and hospital records may also be collected. Your child 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 or your child (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 child's 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 child's 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 child's health or wellbeing. This allows appropriate follow-up to be arranged.
- 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 child's personal information and specimens are kept confidential, information that identifies your child will not be included in any report generated by the **WellKiwis** team AND/OR any study information or specimens sent to the sponsor. Instead, your child will be identified by a unique study code. The **WellKiwis** team will keep a list linking your child's unique code with their 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 child's 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 all three DIVINCI study sites will be put together for analysis. Results on all study participants will be grouped together in an 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.shivers.org.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.

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 you or your child's vaccination and respiratory illness/conditions and non-health related information such as demographics.

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.
- Yours and your child's data will be retained for at least 10 years after the youngest participant 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.
- 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 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.

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. You also have the right to request that any information you disagree with is corrected.

If you have any questions about the collection and use of information about you, you should 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

Email: wellkiwis@esr.cri.nz

For Māori cultural support (Māori Impact Team – ESR), please contact:

Phone: 0800 493 555

Email: 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: hdec@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 health study.

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**.



WellKiwis

influenza study



Te Whatu Ora
Health New Zealand



This study is being conducted at the Institute of Environmental Science and Research (ESR), 66 Ward Street, Upper Hutt, New Zealand.

ESR, one of New Zealand's Crown Research Institutes, is leading the study with New Zealand ethics approval. It is a multi-agency collaboration including Lead Maternity Carer (LMC), the Universities of Otago and Auckland, Health NZ | Te Whatu Ora | National Public Health Service | Te Ikaroa. 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 (SJCRH) in Memphis USA.