



Information Sheet

for Parents, Guardians or Caregivers
of WellKiwis Infant Cohort Study Participants

Locality: Wellington

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Phone: 04 529 0600

What information is included in this information sheet?

This information sheet provides information to help you decide whether you want your child to continue as an infant participant of the WellKiwis Influenza Study (i.e. WellKiwis Infant Cohort Study). It includes the reason why we are continuing the study, what we are asking you and your child to do, the risks and benefits of the study, and what happens when the study is finished. Please read this sheet carefully and discuss with your family, whānau, friends, or healthcare providers before deciding whether to continue with the study or not. It is entirely up to you to decide if you want your child to continue in the study for up to another seven years. Your child can stop taking part in the study at any time – no reason needs to be given. Stopping your participation in the study will not affect your child's current or future health care.

What is the WellKiwis Infant Cohort Study?

The WellKiwis Infant Cohort Study aims to follow children over multiple years to see how a child's first or prior encounter to the flu virus or vaccine influences their immune responses to subsequent flu exposures as they grow. Continuing in the study will allow us to follow your child through their childhood years, building on the data and valuable samples already collected. Findings from WellKiwis will help the New Zealand government make choices about flu vaccine recommendations and make decisions about how to reduce the impact of flu infection in the community. The study will also provide information that can be used to make more effective and longer lasting flu vaccines in the future and better prepare for pandemics.

What are we asking you to do in this study?

We will send you a study invitation letter using your existing electronic contact details you provided to us. If you are interested in your child continuing with the study, please read this information sheet, detailing consenting and study activities. If you have any questions, please feel free to get in touch with the WellKiwis team on 0800 493 555 or email (Wellkiwis@phfscience.nz) to discuss the study further.

Consent and Assent: To enrol your child in the study, you will need to complete an online consent form using the link provided in the invitation.

- For children aged 7 years or over, they will need to provide their agreement (assent) to continue in the study. We will send you an email or text with a link to the online assent form, information to help your child understand about providing assent, and a simplified participant information sheet.
- If you have difficulties with the links to the consent and assent forms, you can contact the WellKiwis team and we will help sort it out. Alternatively, you can go to <https://www.wellkiwis.co.nz> to download and print the forms, then sign and return them electronically. Or you can call or email us,

and we will mail the forms to you with a pre-paid return envelope.

Once you have provided consent and your child, if aged 7 years or over, has provided their assent to continue in the study, you and your child will participate in the following yearly study activities (surveys, swab and blood samples), for up to seven further years (2026-2033). The study activities are like the first seven years of the study (2019-2025) – the only difference is that we will also ask you to complete an annual general health survey for your child.

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

- **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 received a flu vaccination or shows any signs of a respiratory illness, such as cough and fever. If their symptoms 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 three surveys outside the flu season; one to check your contact details are still correct, one to ask about general health conditions associated with getting flu or respiratory illness over the last 12 months, and one to ask for anonymous feedback on your experience of the WellKiwis study.

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

Nasal Swab Sample Collection: If you report respiratory symptoms for your child 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 will be 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. As your child gets older, they may prefer to do this themselves under your supervision.
- **Returning the swab:** Once you have taken the swab, package it according to the instructions and then leave it in the agreed place for collection. We will arrange for the safe pick up and transport of your swab to the PHF Science laboratory for testing.
- **Testing the swab:** PHF Science lab staff will test your child's swab for flu, SARS-CoV-2 (COVID-19) 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.
- **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 two blood samples from your child.

Blood Sample Collection: During the study, we will need to collect blood samples from your child during each year as outlined below. The number of samples will vary based on whether your child has the

flu vaccine and/or tests positive for the flu. A trained healthcare professional experienced in taking blood will collect these samples.

- The collection schedule is:
 - **Baseline blood:** This sample is usually collected when you and your child provide consent/assent to continue in the study. However, if we have already collected your child's annual blood sample at the end of the 2025 season, your child does not need to provide a baseline blood sample.
 - **Post-vaccine blood:** If your child receives a flu vaccination, a blood sample will be collected 3-7 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 3-7 weeks later.
 - **Annual blood:** Collected after the flu season, usually during October-December each year. The post-season annual blood sample also serves as the pre-season (baseline) blood for the following year.
- 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. Once your child reaches the age of 10 years, there is the option of having the blood samples collected at Awanui Labs.
- You are welcome to perform a karakia at sample collections.
- **Thank you e-gift card:** Your child will be issued a \$30 e-gift card after each blood or swab sample to recognise their time and effort. This will be sent to your email address.

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 doctor.

What are the benefits of taking part in this study for me and my child?

- You will find out if your child was ill from the flu, SARS-CoV-2 or another respiratory virus during the winter.
- The study nurses will provide you with public health advice when your child is 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 around the world to better prepare us for and respond to pandemics and epidemics and will help to develop effective vaccines against these viruses.

Who is involved in running the WellKiwis Influenza Study?

The New Zealand Institute for Public Health and Forensic Science (PHF Science) is the leading agency for the WellKiwis Influenza Study. It is a member of the SHIVERS (Southern Hemisphere Influenza and Vaccine Effectiveness Research and Surveillance) project family. SHIVERS is a long series of research on the influenza virus, immunity, and vaccine, and the WellKiwis Infant Cohort study is the third in its series (SHIVERS-III).

Here are some other important details about the WellKiwis Infant Cohort Study:

- The WellKiwis Influenza 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).

Our main international collaborators include the St. Jude Children's Research Hospital (SJCRH) in Memphis, USA and Fred Hutchinson Cancer Center (FHCC) in Seattle, USA.

- WellKiwis Infant Cohort has a sister site in Managua, Nicaragua.
- In New Zealand, WellKiwis is a multi-agency collaboration including PHF Science, the Universities of Auckland and Otago, Health NZ Capital, Coast and Hutt Valley, and Awanui Laboratories.
- The New Zealand Northern A Health & Disability Ethics Committee has approved WellKiwis under Reference 2026 AM0952.
- The Lead Investigator for the WellKiwis Infant Cohort Study is Dr. Sue Huang.

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

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

- Nasal swabs will be tested for flu and other respiratory viruses (SARS-CoV-2, respiratory syncytial virus, rhinovirus, enterovirus, parainfluenza virus types 1-3, adenovirus and human metapneumovirus) that may cause symptoms for your child. We will inform you of these results.
- Blood samples will be processed at PHF Science. The processed blood samples will be sent to SJCRH/FHCC as the main testing centres for samples from all three DIVINCI study sites to be tested for antibodies, other immune cells, and specific genes that associate with immune responses (including HLA typing, which looks at natural variations in genes that influence how the immune system responds to infections and vaccines). These tests will show if your child has developed immunity against the flu virus or vaccine.
- Some blood samples may be sent to other collaborators at Universities and Medical Schools such as Mt Sinai, Chicago, Washington, Emory, Rochester, Melbourne, Hong Kong and Stanford for some specific immunology testing that cannot be done at SJCRH/FHCC.
- If you agree, your child's samples may be tested to help answer future questions about influenza and/or other respiratory viruses if required for public health action in the case of an epidemic or pandemic (for example, understanding whether the human population has any pre-existing immunity against a newly emerging pandemic virus). You will not receive the results from analysis done on your child's samples or data for these extended research purposes.

Will I receive the results of the genetic tests? And what will happen to my child's genetic information?

You will not receive the results from tests done on your child's blood samples, including genetic testing, because these test results are not for clinical purposes and have no direct implications for your child's current and future healthcare. The genetic testing performed is limited to understanding immune responses and will not be used to look for unrelated health conditions.

These genetic tests compare samples collected across several years, so it may be many years before the testing is completed. The results of these tests will be published in scientific and medical journals, and you can contact us to get the overall WellKiwis results, however it may be many years before these results are available.

How are the samples stored?

Study samples will be stored securely and retained for 10 years after the youngest participant turns 16 years of age and will then be disposed of safely. With your consent, some de-identified samples may be kept longer for extended health research, including to help respond to pandemics or epidemics.

You may hold beliefs about a sacred and shared value of all or any tissue samples. 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 this; 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 your privacy protected? What happens to the information you provide?

Your and your child's data and testing result information are confidential. This study will comply with all New Zealand laws governing ethical research including the Privacy Act 2020.

During this study, the study researchers, clinical team and laboratory team will record enrolment information about you and your child, and information from your child's participation in the study. This includes your responses to surveys and details you provide in discussions with the WellKiwis team, such as your child's symptoms during the winter surveillance period. If needed, information from your GP and hospital records may also be collected. You 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 your child (e.g. name, date of birth, or address). The following groups may have access to your child's 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 test results.
- If your child's sample tests positive for SARS-CoV-2 the result is required to be reported to the Medical Officer of Health, as COVID-19 is a notifiable disease in NZ.
- 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, or any study information or samples sent overseas. 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 samples, which may be sent and stored overseas:

- The sponsor and its representatives, for the purposes of this study.
- Organisations 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 this study 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 PHF Science and study websites

(www.phfscience.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 your child. It will not be possible to inform you of any individual results once anonymised. You can contact us to get the overall study results. It may be many years before these results are available.

Data linking

In this study we will be linking your child's study information with other data sets (such as vaccination registries and general practice medical records) which include information about your child. This is called data linking. Data linking in this study is required to validate or complete missing information about your child's vaccinations, respiratory illnesses or conditions, and non-health related information such as demographics.

Data and sample storage and duration

Your and your child's electronic data will be stored in password-protected databases. Physical data is stored in filing cabinets at one of PHF Science's secure sites, in a restricted access building.

Your and your child's data and samples will be retained for at least 10 years after the youngest participant turns 16 years of age. With your consent, some de-identified data/samples may be kept for longer for extended health research, including to help respond to pandemics or epidemics.

Rights to access your information

- You have the right to request access to your information held by the research team and to ask for that information to be corrected if you find an error.
- If you have any questions about the collection and use of information about you and your child, please ask the WellKiwis study team.
- You will be provided with results from swabs. You will not be provided with results from blood samples.

Rights to withdraw your information

- You may withdraw your consent for the collection and use of you and your child's information at any time by informing the WellKiwis study team.
- If you withdraw your consent, your child's study participation will end, and the study team will stop collecting information from you.
- If you agree, data and samples collected up until your withdrawal from the study will continue to be used and included in the study.

What if something goes wrong?

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

- Nasal swabs may cause brief pain, itchy nose, eye watering, or sneezing. We minimise risks by providing you with clear instructions and a video tutorial on how to take a nasal swab for your child.
- 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 risks by having trained staff take your child's blood samples.
- If your child was injured in this study, which is unlikely, you would be eligible to apply for compensation from ACC just like if you were injured in an accident at work or at home. 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 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 child's privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that your child cannot be identified. The risk of people accessing and misusing your child's information is currently very small but may increase in the future as people find new ways of tracing information.

- Your child's 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 child's information.
- Genetic research involves risks that the information arising from genetic research may be misrepresented or misused in ways that lead to prejudice, stigma, disrespect, discrimination or other harms to participants, their families and communities. However, the genetic testing performed in this study is limited to understanding immune responses and will not be used to look for unrelated health conditions. The level of risk associated with this type of testing is low.

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@phfscience.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)

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 2026 AM 0952

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



WellKiwis
influenza study