



WellKiwis
influenza study

CONSENT FORM – Infant

BIRTH MOTHER AND INFANT'S NAME

I, _____ (print full name of birth mother)

give my consent to allow my child born on _____ (Date)

to take part in this study as signed in this document.

Infant's name: _____

PLEASE READ THE FOLLOWING INFORMATION

- I have read and understood the WellKiwis Influenza Study participant information sheet.
- I have been able to get the answers to questions I had about this study.
- I understand that taking part in this study is voluntary (my choice), and I may stop my child from taking part in the study at any time. This will not affect the current or future health care of my child.
- I understand that taking part in this study is confidential. My child name, address, other details that could identify my child, will not be used in study reports or any study results shared publicly.
- I understand the privacy of my child's study information is protected by the laws governing ethical research in New Zealand and this study has ethics approval (NTX11.11.102.AM42) from NZ's Health & Disability Ethics Committee (HDEC).
- I agree to an approved auditor appointed by HDEC, or any regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.
- I understand 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.
- I understand the study will provide compensation to cover my time, effort and other study-related costs.
- I understand the compensation provisions in case of injury during the study.
- I understand my child's samples (blood/respiratory swab) and the information I provide will be stored securely for ten years after the study ends or ten years after my child turns 16 years and then will be destroyed with appropriate procedures.
- I understand my child's blood sample will be sent to St Jude Children's Research Hospital (SJCRH) as main testing centre. 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 testing that cannot be done at SJCRC. My child's name and other identifiable information will be removed when the samples are sent overseas.
- I understand my child's study data with a unique study number without any identifiable information will be sent to University of Michigan as data centre that will put the data together from all three study sites for analysis.
- I consent to the WellKiwis staff to collect and process my child information, including information about my child's health.
- I understand my GP will be given my child's test results and I can also request the test results through study staff.
- I understand information may be collected from my child's practice medical records and also from NZ health registries.
- I understand I have the right to check study information and to ask for that information to be corrected, if I find an error.
- I know who to contact if I have any questions about the study.
- I understand the overall study findings will be published in medical papers and on the SHIVERS website (www.shivers.org.nz). I know I can contact ESR for a copy of the overall findings.

YOU CAN CHOOSE WHETHER OR NOT YOU WANT TO CONSENT TO THE FOLLOWING STUDY ACTIVITIES *please tick your response*

I agree my child's samples (blood/respiratory swab) 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 influenza epidemic or pandemic. Yes No

If I decide to withdraw my child from the study, I agree that the information collected about my child up to the point when I withdraw may continue to be processed. Yes No

PARENT/GUARDIAN DETAILS

Birth mother or guardian of child participant's signature: _____

OPTIONAL: Parent or guardian of child participant's signature: _____

Date: _____

Date: _____

Relationship to child: Birth mother/guardian

Relationship to child: _____

Name: _____

Name: _____

Thank you for participating in this study.

For further information please contact Dr. Sue Huang or other study staff at freephone **0800 493555 (08004WELLKIWI)** or Wellkiwis@esr.cri.nz

INSTITUTE OF ENVIRONMENTAL SCIENCE AND RESEARCH LIMITED

Kenepuru Science Centre: 34 Kenepuru Drive, Kenepuru, Porirua 5022 | PO Box 50348, Porirua 5240, New Zealand
T: +64 4 914 0700 F: +64 4 913 9609

NCBID – Wallaceville: 66 Ward Street, Wallaceville, Upper Hutt 5018 | PO Box 40158, Upper Hutt 5140, New Zealand
T: +64 4 529 0600 F: +64 4 529 0633

www.esr.cri.nz