



Consent Form

Extension of the WellKiwis Infant Study

Child's Name:

I, _____, give my consent to allow my child

(print full name of parent/guardian)

born on ____/____/____ to continue in this study as signed in this document.

dd/ mm/ yyyy)

1. I have read and understood the WellKiwis Infant Cohort Study participant information sheet and invitation you sent to me using my existing electronic contact details I provided you.
2. I have been given sufficient time to consider whether or not my child should participate in this study.
3. I have had the opportunity to use a legal representative, whānau/family support or a friend to help me ask questions and understand the study.
4. I understand that taking part in this study is voluntary (my choice), and I may withdraw my child from the study at any time without this affecting my child's current or future health care.
5. I know who to contact if I have any questions about the study.
6. I consent to the research staff collecting and processing my child's information, including information about my child's health.
7. I understand that my child's study information may be linked with other data sets which include my child's information, such as vaccination registries and general practice medical records.
8. I understand that taking part in this study is confidential and that no material which could identify my child personally will be used in any study reports.
9. I consent to my child's information and specimens being sent overseas.
10. I understand that my child's name and other identifiable information will be removed when data and/or samples are sent overseas, and a unique study code will be used for my child.
11. I understand that my child's blood samples will be sent to St Jude Children's Research Hospital (SJCRH) and Fred Hutchinson Cancer Centre (FHCC) as the main testing centres. Some 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 testing that cannot be done at SJCRS/FHCC.
12. I understand that my child's sample will undergo genetic testing (HLA typing) for research purposes, that I will not receive individual results for these genetic tests, and that their genetic information will be stored securely and used only in anonymised form for research and publication.
13. I understand that my child's study data will be sent to University of Michigan as the data centre that will process data from all study sites (Wellington, Nicaragua).
14. I understand that the privacy of my child's study information is protected by the laws governing ethical research in New Zealand and that this study has ethics approval from NZ's Health & Disability Ethics Committee (HDEC).

15. I agree to an approved auditor appointed by HDEC, or any regulatory authority or their approved representative, reviewing my child's relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.
16. 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.
17. I understand that the study will provide koha to cover my time, effort and other study-related costs.
18. I understand the compensation provisions in case of injury during the study.
19. I understand that my child's samples (blood and nasal swab) and the information I provide for primary study purposes will be stored securely for at least 10 years after the youngest participant turns 16 years of age and will then be destroyed with appropriate procedures.
20. I understand that I will be provided with results from swab testing. I will not receive results from blood samples. I can request the overall WellKiwis results through study staff.
21. I understand that I have the right to check study information and to ask for that information to be corrected if I find an error.
22. I understand that the overall study findings will be published in medical papers and on the PHF Science and study websites (www.phfscience.nz, www.wellkiwis.co.nz). I know I can contact PHF Science for a copy of the overall findings.

You can choose whether or not you want to consent to the following study activities.	<i>Please circle your response</i>	
I agree that my child's samples (blood and nasal swabs) 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 these extended research purposes, I understand that my child's de-identified samples may be kept longer than those for primary study purposes and I will not receive the results from this testing.	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

Person Providing Consent for Child Participant (Parent, Guardian, Caregiver)	
Name:	
Signature:	Date:
Relationship to child:	
Optional (Other Parent, Guardian, Caregiver)	
Name:	
Signature:	Date:
Relationship to child:	

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@phfscience.nz