You are invited to take part in a study on the accuracy of the National Immunisation Registry. We want to hear from guardians who have complete immunisation pages in their children’s Well Child Tamariki Ora (Plunket) Book. Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason, and it won’t affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you’d like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 5 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

**WHAT IS THE PURPOSE OF THE STUDY?**

The National Immunisation Register (NIR) is a computerised information system that has been developed to hold immunisation details of New Zealand children. Please visit the Ministry of Health website for more information (health.govt.nz). This study will help us understand if data about your child’s immunisations are being entered correctly onto the National Immunisation Registry. To do this we will compare the immunisations recorded in your child’s Well Child Tamariki Ora (Plunket) Book to those on the National Immunisation Registry. This study will help us understand if there are any errors in the National Immunisation Registry, and what types of errors they might be.

This study has been approved by the Health and Disability Ethics Committee [XX].
This study has been funded by the University of Auckland. The funders of the study will not know the name of anyone who has been interviewed.

**Contact Details:**

**Dr Anna Howe** (Principal Investigator)  
Department of General Practice and Primary Health Care, University of Auckland  
Phone: 09) 923 2310  
Email: plunket-book-study@auckland.ac.nz

**Dr Janine Paynter** (Co-investigator)  
Department of General Practice and Primary Health Care, University of Auckland

**Dr Esther Willing** (Co-investigator)  
Kōhatu – Centre for Hauora Māori, Division of Health Sciences, University of Otago

**Hannah Chisholm** (Research Assistant)  
Department of General Practice and Primary Health Care, University of Auckland

**WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?**

We are inviting you to be involved in this study because you have a complete record of your child’s immunisations recorded in their Well Child Tamariki Ora (Plunket) Book. If you choose to take part, the lead researcher or another researcher will ask you for your child’s National Health index number and for a copy of your child’s Well Child Tamariki Ora (Plunket) Book immunisation page. This will take no longer than 20 minutes. An example of a blank Well Child Tamariki Ora (Plunket) Book immunisation page is provided below:
There is no need for you to visit the researchers, this can be done at your home, or wherever suits you. Your child’s National Health Index number will be used to access their National Immunisation Records (national computerised immunisation data). This is because we would like to compare the national immunisation data to the Well Child Tamariki Ora (Plunket) Book immunisation data. There is nothing else that you need to do.

**WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?**

This work is vital as currently there is no indication of the type or magnitude of error within the NIR, despite the considerable use of the NIR in NZ for monitoring and research. No dataset is without data entry error, but to our knowledge this is not monitored and therefore has not been quantified. The implication of this is that any use of the NIR introduces unknown error, both in type and magnitude. The future benefit of this study is that it will help us understand what types of errors exist, if any, in the NIR. If the error is low, researchers, and the public through official government releases, can have faith in the results produced using the NIR.

We will be recruiting guardians and their children who have received their childhood immunisations. Participation in this study may make you consider your thoughts about vaccination. If this study triggers uncomfortable thoughts, you may end your participation in the study up to two weeks after you have provided us with your data.

Whenever you take part in a study where information is collected, there is always the remote risk of loss of privacy from a data leak. We take data security very seriously – please see below (*What are your rights?*) for how we will protect your privacy.

**WHO PAYS FOR THE STUDY?**

You will not incur any costs for participating in this study. If you would prefer to post your Well Child Tamariki Ora (Plunket) Book immunisation data to us, the study will cover this cost.

In acknowledgement of your time, all guardians returning participant data will go into the draw to win one of 5 $100 Prezzy cards, or similar.

**WHAT IF SOMETHING GOES WRONG?**

If you were injured in this study, for example you had an accident on the way to the post office, you would be eligible to apply for compensation from ACC just as you would be 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 won’t affect your cover.

**WHAT ARE MY RIGHTS?**

Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason, and it won’t affect the care you or your child receive. If you do want to take...
part now, but change your mind later, you can pull out of the study at any time up to two weeks after you provide the data.

You have the right to see any information we collect about you as part of the study, just ask the lead researcher using the contact details above.

Your privacy and confidentiality are very important. Your name or your child's name will not be on the information about your participation. The data you provide will be kept on a computer that is password protected. Your consent form will be kept in a locked filing cabinet. Any person using the data you have supplied will sign a confidentiality agreement. No information about you or your child will be given to anyone outside of the research team.

**WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?**

We would be happy to provide you with a summary of what we found out in the study. This might take up to one year after your participation.

Study material will be destroyed by confidential document destruction after ten years. Computer files will be kept for at least ten years, then deleted from the computer. The research team will be responsible for the safe storage of your information.

**WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?**

If you have any questions, concerns or complaints about the study at any stage, you can contact:

*Anna Howe (Principal Investigator) or Hannah Chisholm (Research Assistant)*
Phone: 09) 923 2310  
Email: plunket-book-study@auckland.ac.nz

For Māori health support please contact:

*Dr Esther Willing*  
*Ngāti Toarangatira, Ngāti Koata, Ngā Ruahine*  
Phone: (03) 470 3490  
Email: esther.willing@otago.ac.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

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS  
Email: hdecs@moh.govt.nz
## Consent Form

Please tick to indicate you consent to the following:

<table>
<thead>
<tr>
<th>Statement</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>I have been given sufficient time to consider whether or not to participate in this study.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>I have had the opportunity to use a legal representative, whanau/family support or a friend to help me ask questions and understand the study.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>I consent to the research staff collecting and processing my information, including information about my health.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>If my child is between the ages of 8-14 years old, I have explained the study to them, including their right to not participate.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>I know who to contact if I have any questions about the study in general.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>I understand my responsibilities as a study participant, which include explaining the study to my child.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>I wish to receive a summary of the results from the study.</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

If yes, postal/email address: _______________________________  
______________________________________________________

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**Declaration by participant:**
I hereby consent to take part in this study.

**Participant’s name:**

Signature: ___________________________  Date: ___________________________

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Lay study title: The Plunket Book study  
PIS/CF version no.: 2  
Dated: 1 July 2019