PIPPA TAMARIKI
Paracetamol and Ibuprofen in Primary Prevention of Asthma in Tamariki

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Participant Information Sheet

Study title:	**Paracetamol and Ibuprofen in Primary Prevention of Asthma in Tamariki (PIPPA Tamariki)**		
Locality:	**[Insert site name]**	Ethics committee ref:	**17/NTA/233**
Lead investigator:	**Professor Stuart Dalziel**	Contact phone number:	**Study 0800 747 728**

Your baby is invited to take part in a study to find out whether receiving paracetamol or ibuprofen in the first year of life affects the risk of having asthma at 6 years of age.

This Participant Information Sheet will help you decide if you'd like your baby to take part. It sets out why we are doing the study and what you and your baby's participation would involve. It also sets out what the benefits and risks to your baby might be, and what happens after the study ends.

We will go through this information with you and answer any questions you have. Before you decide you may want to talk about the study with other people, such as family, whānau (for ADHB and CCDHB)/whaanau (for CMH), friends, or healthcare providers. Feel free to do this.

This document is 9 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

- Asthma is one of the most common illnesses affecting children and adults in New Zealand.
- Despite better medical care, the number of people that have asthma has been rising.
- We don't know why this is the case.
- Some studies suggest that exposure to pain and fever medicines in early childhood may influence the risk of developing asthma.
- However, this has not been proven.
- This study aims to find out if giving babies either paracetamol or ibuprofen when unwell in the first year, alters the chance of having asthma at 6 years old.
- There has never been a study directly comparing the long-term effects of the common pain and fever medicines used in babies, such as paracetamol and ibuprofen, on asthma. Common names for paracetamol include: Pamol, Parapaed, Junior Parapaed, and Paracare. Common names for ibuprofen include: Brufen, Nurofen Junior, Fenpaed, and Panafen.
- This study is being funded by the Health Research Council of New Zealand.
- This study has been approved by the Northern A Health and Disability Ethics Committee, Reference No: **17/NTA/233**

ABOUT PARACETAMOL AND IBUPROFEN

- Paracetamol and ibuprofen have both been widely used for many decades for pain or fever in babies.
- Paracetamol is the most common medicine given to babies in the first year of life.
- Ibuprofen is also commonly used in babies and children for pain or fever.
- Paracetamol and ibuprofen both have excellent safety track records in babies when taken as prescribed.
- Although paracetamol is only given as needed, over 19 out of 20 babies in New Zealand have received at least one dose of paracetamol by 9 months of age.
- Sometimes babies receive both paracetamol and ibuprofen for fever and/or pain.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

Here is a brief outline:

Here are the details:

- **Consent:** If you agree to your baby taking part in the study, we will ask you to sign the Consent Form which you can read at the end of this Information sheet. Normally we will ask you to sign the Consent Form on a tablet or iPad.

- **Giving Information:**
  - We will collect some information from you including:
    - Your contact details, and those of your partner.
    - Contact details of another adult who is not in the same household.
    - Your pregnancy history.
    - Your own history of asthma, eczema and hayfever.
    - Your lifestyle choices and living conditions.
    - Your baby's father's history of asthma, eczema and hayfever.
    - Your baby's birth and medical history.
    - Details (name, date of birth, allergies and weight) of any other children in your household under the age of 10 years.

- **Random allocation to a medicine group:**

- Your baby will be assigned to either 'the paracetamol group' or 'the ibuprofen group'. This means we would like your baby to receive only one medicine, and only when needed for fever and/or pain until 1 year of age. The medicine would be paracetamol for the paracetamol group, and ibuprofen for the ibuprofen group.
- You will not be able to decide which group your baby will be in. This allocation will be random (like the toss of a coin).
- You and the researchers will know which group your baby has been assigned to. We will also tell your baby's family doctor and record it on your baby's hospital records.
- We will send the medicine to you, or give you free prescriptions for the study medicine (free from any pharmacy), until your baby is 1 year old.
- Each time we check in with you, we will supply more medicine or provide another prescription as required. You will be able to request more study medicine at any time by phone or email, or through our website or Facebook page.
- Until your baby's first birthday it is very important that you give your baby only the assigned study medicine, for fever and/or pain, and not the other medicine.
- If you have had a multiple birth (e.g. twins), and each of your babies is enrolled in the study, they will all be assigned the same study medicine.
- To avoid possible confusion, we will send you the same study medicine for all the children aged under 10 years who live with you and your baby (or provide you with a prescription). We will do this until your baby turns 1 year old. If you do not want us to do this, please tell us.

- **Keeping records (Study Diary):**
  - We will provide you with a paper Study Diary and a link to a web page Study Diary, which you can access via your phone, computer, or touchscreen device. Until your baby is 1 year old, we want you to record each time you give your baby the study medicine and why. We also want you to record any other medicine you give your baby until she or he is 1 year old. You can record all this in the paper diary or the web page diary.
  - In some instances, your baby's doctor may decide your baby needs another medicine for fever and/or pain, as well as the one your baby has been assigned to. If this happens, it is important that you also record this in the Study Diary.

- **Questionnaires:**
  - We will contact you about completing simple questionnaires when your baby is:
    - 1 month old.
    - 3 months old.
    - 6 months old.
    - 9 months old.
    - 1 year old.
    - 3 years old.
    - 6 years old.
  - The questionnaires ask about your baby's health and medicine use. They also include questions about other people in the household.
  - You may answer the questionnaires over the telephone or online.
  - The questionnaires will vary in length. Most will take only 5 to 10 minutes. The 1 year questionnaire will take 10 to 20 minutes.

- We will send reminders to you to complete each questionnaire, or to plan a call, 7 to 14 days ahead of the desired date. We can do this by email or text. If we are unable to get hold of you (and you have agreed), we may visit your home address to confirm your contact details.

COLLECTION OF HEALTH DATA

- **Collection of your baby's health data:**
  - We will ask for your consent for us to collect your baby's health data. We will also track your baby's use of the health system and their electronic health data. For example, Emergency Department (ED) visits, hospital admissions, prescription records and the B4 School Check. We do this using their unique hospital number. This number is called a National Health Index (NHI) number. We will do this until your baby is 6 years old.

- **Collection of health data about other children under 10 years of age:**
  - We want to make sure that other children in the household under 10 years old, for whom we have prescribed the study medicine, have not come to any harm. In the questionnaires we will ask about their health and also record their weight. This is so that we can provide the right dose of study medicine for them.
  - If you have other children, we ask for your consent for us to collect your other children's health data. For safety monitoring we will track your other child/ren's ED visits and hospital admissions. We would do this using their NHI. We will only do this until your baby turns one.
  - You will be asked to sign a consent form for each child under 10 years of age for whom you wish to receive study medicine.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

- **Your baby's involvement in the PIPPA Tamariki study will provide you the opportunity to**:
  - Play an active role in their health care by keeping records about their health in a Study Diary.
  - Receive regular and careful attention from a research team that includes doctors and nurses.
  - Help others by contributing to medical research.
  - Have easy access to free prescriptions for paracetamol or ibuprofen for your baby and other children in the household under 10 years of age.

- **The use of either medicine in standard doses, for fever and/or pain, is thought to be safe and acceptable. As with any medicines, there are some rare side effects:**
  - Using too much paracetamol (i.e., more than the standard doses) can cause liver damage.
  - Using too much ibuprofen (i.e., more than the standard doses) can cause stomach upset (this is uncommon in babies).
  - Using ibuprofen every day for many weeks or months may cause kidney damage.
  - Some studies suggest that giving ibuprofen for viral infections may be linked with more severe infections. No one knows this for sure, and this study can also help answer this question.

- **If your baby's fever or pain persists despite regular paracetamol or ibuprofen they must be seen by a doctor.**

WHO PAYS FOR THE STUDY?

There is no cost to you for taking part in this study. The prescriptions and medicines used are free.

WHAT IF SOMETHING GOES WRONG?

If your baby, or other child/ren, is injured because of being involved in this study, which is unlikely, they would be eligible for compensation from ACC. (Just as they would be if they were injured in an accident at school or at home). You would have to lodge a claim with ACC, which may take some time to assess. If your claim was accepted, you would receive funding to assist in your baby's recovery.

WHAT ARE MY RIGHTS?

- Taking part in the study is entirely your choice.
- You do not have to enrol your baby in this study. If you choose not to take part, it won't affect the care you, or your baby, receives.
- You have the right to access the information that we have collected about you, your baby and other children as part of the study.
- You have the right to withdraw your baby from the study.

PRIVACY AND CONFIDENTIALITY OF STUDY INFORMATION

With respect to your personal information:

- All paper-based and electronic records for this study will be kept confidential. The information will be held securely by the research team and will only be available to research staff and those who are auditing the study.
- Your study-related information will be labeled with a code. The link between the code and your identifying information will be kept confidential and be held by the research staff only.
- All study data that is reported on, published, or shared with other research teams will be 'de-identified'. This means that you and your baby cannot be identified as a result of that data being seen.
- The de-identified information collected in this study may be used for other research studies in the future. These studies would need to be approved by a Health and Disability Ethics Committee.
- Sometimes, the Northern A Health and Disability Ethics Committee or an auditor may want to make sure the research team is running a study properly. They will have secure access to the information collected during this study to check this.
- Your baby's participation in the study, including presentation in any promotional material, will not be revealed without your explicit written consent.

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

- You are free to pull out of the study at any time, without giving any reasons. This will not affect any care that you or your baby will receive in the future.
- Any data we collect from you, or about your baby and other children, until the time you pull out of the study will be included in our analysis.
- We expect there will be many reports coming out of this large study. We intend to publish all of our results on our website and in medical journals. You may ask to receive these findings personally if you wish.
- If you wish to receive a summary of the final results of the study, we will send this to you. This is expected to be in 2028.
- The babies involved in this study are a very important group. We may wish to approach the babies in this study in the future for longer term follow up research. All future studies would first need ethics approval.
- During the study, data will be stored securely by the Director of the Medical Research Institute of New Zealand.
- After completion of the study, data will be stored securely by the Head of Department, Department of Paediatrics: Child and Youth Health, The University of Auckland. Paper-based records will be kept until the youngest participant has reached 28 years of age and then destroyed. Electronic data will be archived and stored indefinitely. Only de-identified data will be used after the participants' sixth birthday, unless further consent or ethical approval has been obtained.
- If in the future, after completion of the trial, if a participant wishes to have their electronic data fully anonymised or removed from the archive, they can request this by contacting the investigators or the Department of Paediatrics.

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 any of these people.

The Principal Investigator is Professor Stuart Dalziel:

Director of Emergency Medicine Research
Children's Emergency Department,
Auckland District Health Board, New Zealand
Phone +64 9 3074949
Email: sdalziel@adhb.govt.nz

The person who is coordinating this study at your hospital is:

[enter Principal Investigator for this site:
enter Doctor's name
enter phone number
enter email address]

For more details OR To talk to a PIPPA Tamariki Research Assistant contact:

Phone: 0800 PIPPA T (0800 747 728)
Email: pippatamariki@auckland.ac.nz
Web: www.pippatamariki.ac.nz
Facebook: PIPPA Tamariki

Cultural Support: **If you need Māori cultural support, you can contact:**
[Local contact details to be entered
Phone
Email]

If you need Pasifika cultural support, you can contact:

[Local contact details to be entered
Phone
Email]

If you want to talk to someone who is not involved with the study

You can contact an independent Health and Disability advocate on:

Phone: 0800 555 050
Email: advocacy@hdc.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

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CONSENT FORM for Baby

If you need an INTERPRETER, please tell us.

Participant statement:

I have read, or have had read to me, in a language I understand, and I understand, the Participant Information Sheet.		
I have been given sufficient time to consider whether or not to participate in this study.		
I have had the chance to use whānau (whaanau)/ family support, a friend, or a legal representative to help me ask questions and understand the study.		
I am satisfied with the answers I have been given regarding the study. I have a copy of this consent form and information sheet.		
I understand that taking part in this study is voluntary (my choice). I understand that I may withdraw my baby from the study at any time without this affecting my baby's medical care.		
I consent to the research staff collecting and processing my baby's information, and collecting information about my health.		
I understand that my baby's participation in this study is confidential and that no material which could identify me or my baby will be used in any reports or promotional material on this study without my written consent.		
If I decide to withdraw from the study, I agree that the information collected about myself and my baby, up to the point when I withdraw, may continue to be processed.		
I consent to the research staff using my baby's available electronic health data, including from the Ministry of Health and District Health Board databases.		
I consent to my baby's GP or current health provider being informed about my baby's participation in the study.		
I agree to an approved auditor, appointed by the Ethics Committees, reviewing my baby's relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.		
I understand the compensation provisions in case of injury during the study.		
I know who to contact if I have any questions about the study.		
You may contact me about future PIPPA Tamariki research after my baby turns 6 years of age.	Yes ☐	No ☐
I wish to receive a summary of the final results from the study.	Yes ☐	No ☐
I agree for a member of the study team to visit me at home, to confirm my contact details, if the team have been unable to contact me by phone.	Yes ☐	No ☐

Declaration by parent/caregiver:

I, (Full name),

Caregiver of (NHI, or name of baby if known),

hereby consent to my baby taking part in this study.

Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the parent/caregiver, and have answered the parent's/caregiver's questions about it. I believe that the parent/caregiver understands the study and has given informed consent for their baby to participate.

Researcher's name:

Signature: Date:

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CONSENT FORM for other children under 10 years of age

Please note: A new form is required for each child

If you need an INTERPRETER, please tell us.

Participant statement:

I have read, or have had read to me, in a language I understand, and I understand, the Participant Information Sheet.
I have been given sufficient time to consider whether or not to participate in this study.
I have had the chance to use whānau (whaanau)/ family support, a friend, or a legal representative to help me ask questions and understand the study.
I am satisfied with the answers I have been given regarding the study. I have a copy of this consent form and information sheet.
I understand that taking part in this study is voluntary (my choice). I understand that I may withdraw my child from the study at any time without this affecting my child's medical care.
I consent to the research staff collecting and processing my child's information.
I understand that my child's participation in this study is confidential and that no material which could identify my child will be used in any reports or promotional material on this study without my written consent.
If I decide to withdraw from the study, I agree that the information collected about my child up to the point when I withdraw, may continue to be processed.
I consent to the research staff using my child's available electronic health data, including from the Ministry of Health and District Health Board databases.
I consent to my child's GP or current health provider being informed about my child's participation in the study.
I agree to an approved auditor, appointed by the Ethics Committees, reviewing my child's relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.
I understand the compensation provisions in case of injury during the study.
I know who to contact if I have any questions about the study.
I wish to receive a summary of the final results from the study. Yes ☐ No ☐

Declaration by parent/caregiver:

I, (Full name),

Caregiver of (child's name),

hereby consent to my child taking part in this study.

Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the parent/caregiver, and have answered the parent's/caregiver's questions about it. I believe that the parent/caregiver understands the study and has given informed consent for their child to participate.

Researcher's name:

Signature: Date: