# PARTICIPANT INFORMATION SHEET

## Psoriasis and Control Biomarker Subgroups and Future Unspecified Research (Optional)

**Study title:** Maternal Psoriasis and Infant Neurodevelopmental Outcomes (MaPINO) Study

You have already agreed to take part in the Maternal Psoriasis and Infant Neurodevelopmental Outcomes (MaPINO) study. This participant information sheet tells you about an optional sub study which will be conducted in a small number of subjects already enrolled in the main study. This information sheet and consent form is in addition to the main study consent form that you have already signed.

Whether or not you take part in the optional sub study is your choice. If you do not want to take part, you do not have to give a reason, and it will not affect the care you receive or your participation in the main study. 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, whanau, friends, or healthcare providers.

If you agree to take part in this sub study, please sign the relevant consent forms on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Forms to keep.

This document is 16 pages long, including the Consent Forms. Please make sure you have read and understood all the pages.

**What is the purpose of the study?**

In this part of the study, we are investigating *how* inflammation in pregnancy might affect brain development. We will do this by:

1. Testing your blood samples during pregnancy and at delivery for indicators of inflammation, these molecules are called cytokines

2. Testing your baby's blood samples at delivery for indicators of inflammation (cytokines and immunophenotyping) and to find out the activity of different genes (mRNA and DNA analysis) at delivery

We will recruit 30 pregnant women with psoriasis and 30 pregnant women without psoriasis who are involved in the main study to this part of the study.

**Who can take part in this study?**

Pregnant women with and without psoriasis who are less than 15 weeks pregnant (this may be extended to less than 20 weeks pregnant if necessary to achieve the required sample size).

To take part in this study, you must be planning to deliver your baby at an Auckland Hospital (Auckland City Hospital, Middlemore Hospital, North Shore Hospital or Waitakere Hospital) or primary birthing unit.

**What does the study involve for me, my child and our family?**

The study will involve:

1. A 5ml (1 tsp) blood sample being collected in each trimester of pregnancy (12-14 weeks, 24-28 weeks and 34 weeks gestation) and at delivery. We will coordinate this blood test with other blood tests that you need whenever possible, but you may need a separate blood test on one or two occasions. These blood samples will be analysed for the inflammatory indicators called cytokines. The blood tests can be done at your local blood collection centre.
2. A 10-15 ml (2-3 tsp) blood sample being collected from your baby at delivery. This will be cord blood whenever possible. The blood sample will be used to look at gene activity (mRNA, DNA and protein analysis).

**What happens to my child's and my blood samples after they have been collected?**

The blood samples will be sent to LabPlus, Auckland. The blood samples for inflammatory marker testing will then be stored and analysed at the Centre for Brain Research, Grafton, Auckland. Additional testing may be done at School of Biological Sciences, University of Auckland and Children's Medical Research Institute, New South Wales, Australia.

The blood samples for gene activity testing, will be sent to the Australian Genomic Research Facility (AGRF). Preparation of the blood samples for analysis will take place at AGRF Adelaide, South Australia, and the samples will be analysed at AGRF, Melbourne, Victoria, Australia. The samples will be discarded by AGRF after analysis and cannot be returned to you.

The samples at the Centre for Brain Research will be stored for ten years, then destroyed according to standard laboratory practice or returned to the participant on request.

**Cultural Statement**

We recognise that knowledge is taonga and the research will be conducted in accordance with the principles of Māori data sovereignty. Taking of blood is a major cultural issue for Māori as it is linked to whakapapa and continuation of Māori as a nation. For some Māori, blood is considered tapu and imbued with wairua. The study has been reviewed by the Director of Maori Health Research across the Auckland District Health Board as part of the ethics approval process and where possible the care and storage of blood samples within New Zealand align with tikanga Māori. All participants will have the option for karakia before their sample is sent overseas or destroyed. However after the samples are sent overseas, they will be processed according to Australian government research laboratory regulations rather than New Zealand guidelines.

**Future Research**

You have the further option of participating in future research related to the study. The additional research may include:

1. Testing your blood samples taken in the first trimester to find out the activity of different genes (mRNA). We will compare your results with the results of your baby.
2. Testing you and your baby's genes (DNA) to help interpret the results regarding gene activity (mRNA).
3. Unspecified purposes which relate to our research question.
4. Unspecified purposes which relate to psoriasis, brain development, inflammation or inheritance of genetic information

**What will the future research involve for me, my child and our family?**

1. We will collect an additional 2-3 tsp (10-15 ml) of blood from you in addition to the bloods collected at 12-14 weeks of pregnancy. We will also collect a blood sample for the indicators of inflammation (cytokines) at delivery. You will not need an additional blood test. The extra samples will potentially be used for mRNA analysis and DNA/genetic sequencing.
2. Two mls of the cord blood collected from your baby will be used for DNA/genetic sequencing.

**What happens to my child's and my additional blood samples after they have been collected?**

The blood samples will be sent to LabPlus Auckland, and then stored at the Centre for Brain Research, Auckland. If future testing proceeds, the samples most likely will be analysed at the Australian Genomic Research Facility (AGRF), The University of Auckland and Children's Medical Research Institute. The samples will be discarded by each laboratory after analysis and cannot be returned to you, but samples at the Centre for Brain Research will be stored for ten years and can be returned to the participant on request.

**What are the possible benefits of the study?**

The study will have no direct benefits for you but will help in the care of pregnant women with psoriasis and other inflammatory conditions in the future. Participating in future research may help maximise our findings from the first part of the study.

**What are the possible risks of the study?**

This study is an observational study only so you will not be asked to test any treatments.

The blood test may cause mild and temporary discomfort. We will arrange for the blood tests to be taken at the same time as other blood tests whenever possible.

The study involves looking at the overall activity of 20,000 genes. Genes are the instructions that tell your body how to work. Sometimes genes are copied wrong and this can cause disease. We will not be looking at each gene in detail and therefore it is unlikely that we will discover extra health information (information not related to the research and that we were not looking for) that is important to your or your baby's health. These are what we call 'incidental findings'. If this situation arises, we will seek advice from a clinical geneticist, and we will inform you according to your wishes indicated on the consent form below. We will not provide feedback on conditions that; 1) are not likely to be of serious health or reproductive importance, 2) whose likely health or reproductive importance cannot be accurately determined, or 3) for which there is no prevention or treatment. If you do not wish to be informed of an incidental finding that will be important to your child's health, we will contact you and your child's GP when your child reaches the age of 16 years to give your child the option of whether or not they would like to be informed of the finding.

If we do inadvertently discover something of major health significance that is reported back to you, it is important to note that this information could be considered 'prior knowledge' of a medical condition for disclosure in private health insurance policies. This knowledge may potentially impact on your right to receive insurance cover for the medical condition.

**Will I be informed of the results of the study and any future research?**

If you would like a copy of the results of the study and any future research, please indicate this on the consent form below and we will send you a summary of the study results once the study is completed.

**How will my child's and my information be stored and what are the risks to my privacy?**
The blood samples will be labelled with your unique study code. Only the research team will have access to the study log that can identify you using your study code. All study investigators have signed confidentiality agreements with their respective institutions. The overseas laboratory will not have any access to identifiable information.

The data from your and your baby's samples will be stored on a secure data repository at the University of Auckland using only your study code. The data will be stored for 10 years after the youngest participant turns 16 year of age.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. No material that could personally identify you will be used in any reports on this study.

**Can I access my child and my information?**

You have the right to request access to your information held by the research team.

If you have any questions about the collection and use of information about you, you should ask a member of the research team (details below).

**Can I change my mind about participating in this study?**
Yes. If you decide to withdraw from the study, a copy of your study information can be sent to you on request and your study record will be destroyed from the study files. If your data has already been analysed at the time of withdrawal, the data will remain in the study results, but your data will be excluded from any further analyses.

Any blood samples that have not been sent overseas can be returned to you on request or will be destroyed. Blood samples that are sent overseas are destroyed after analysis.

**What if something goes wrong?**

In the unlikely event that you are injured in this study, 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.

**Who is sponsoring the study?**
The study sponsor is Auckland District Health Board. The study is funded by the Neurological Foundation of New Zealand.

**Where can I get more information about the study or if I have concerns?**
If you have further questions about this study, please contact research nurse, Susan Law, at susanlaw@adhb.govt.nz, or the coordinating investigator, Dr Hannah Jones, at hannahj@adhb.govt.nz, phone 09 307 4931.

If you would like to talk to someone who isn't involved with the study, you may contact an independent health and disability advocate. Please phone 0800 555 050 or email advocacy@advocacy.org.nz. Further information can be found at www.advocacy.org.nz. Alternatively, you may discuss the study with your general practitioner or health professional.

For Māori health support, please contact Rhonda Holloway (Ngāti Rangitihi), Clinical Nurse Specialist - Kaiārahi Nāhi, Starship Child Health. Phone: 021327125; email rhondah@adhb.govt.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study. Phone 0800 4 ETHIC or email, hdecs@health.govt.nz.

# CONSENT FORM

# Psoriasis and Control Biomarker Subgroups

## Maternal Psoriasis and Infant Neurodevelopmental Outcomes (MaPINO) Study

**Ethics Approval No.: 2021 FULL 11776**
**Coordinating Investigator:** Dr Hannah Jones, Paediatric Neurologist

**Please tick to indicate you consent to the following:**
*(If you need an interpreter, please tell us.)*

- I have read, or have had read to me, the information sheet about this study, and I understand what the study involves.

- I have been given sufficient time to consider whether or not my child and I will participate in this study.

- I have had the opportunity to obtain whanau / family support or a friend to help me ask questions and understand the study.

- I am satisfied with the answers I have been given regarding the study

- I understand that I will be given a copy of this consent form and the information sheet to keep.

- I understand that my child and my taking part in this study is voluntary (my choice) and that we may withdraw from the study at any time without this affecting our medical care.

- If I decide to withdraw my child and myself from the study, I agree that the information collected about us up to the point when we withdraw from the study may continue to be processed.

- I consent to the research staff collecting and processing information about my child's and my own health.

- I agree to my and my child's blood samples being sent overseas for genetic testing where they will

be disposed of according to their standard laboratory protocol

- I am aware that the genetic testing may produce unexpected results of potential health or reproductive significance that are unrelated to the research (incidental findings)

- I understand that my child and my participation in this study is confidential and that no material, which could identify either of us personally, will be used in any reports or presentations on this study.

- I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant 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.

- I know who to contact if I have any questions about the study in general.

- I wish to be informed of any additional findings regarding my child or me that have health or reproductive significance, and where prevention and/or treatment are available — YES ☐ NO ☐

- I would like a karakia spoken over my and my child's blood samples before they are sent overseas — YES ☐ NO ☐

- For any blood samples remaining in New Zealand I would like them: (Please tick which option applies)
  - i) Returned to me at the completion of the study ☐
  - ii) Disposed of with a karakia according to culturally appropriate laboratory protocol ☐
  - OR
  - iii) Disposed of according to standard laboratory protocol ☐

- I wish to receive study updates over the course of the study period. — YES ☐ NO ☐

- I wish to receive a summary of the results from the study. YES ☐ NO ☐

**Declaration by the Participant:**

I hereby consent to my child and me taking part in this study.

Participant's name: _____

Participant's signature: _____

Date: _____

Contact phone number: _____

Contact email address: _____

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant and have answered all the participant's questions.

I believe that the participant's parent/guardian understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____

# CONSENT FORM (Child) - Biomarker Subgroups

## Maternal Psoriasis and Infant Neurodevelopmental Outcomes (MaPINO) Study

*(To be signed after delivery)*

- I hereby consent to my child taking part in this study
- I understand that my child's involvement in this study is voluntary and I may withdraw him/her from the study at any time without this affecting their medical care
- If I decide to withdraw my child from the study, I agree that the information collected about them up to the point when I withdraw them from the study may continue to be processed.
- I consent to the research staff collecting and processing information about my child's health
- I agree to my child's blood samples being sent overseas where they will be disposed of according to their standard laboratory protocol
- I am aware that the genetic testing may produce unexpected results of potential health or reproductive significance that are unrelated to the research (incidental findings)
- I understand that my child and my participation in this study is confidential and that no material, which could identify either of us personally, will be used in any reports or presentations on this study.
- I know who to contact if I have any questions about the study in general.
- I wish to be informed of any additional findings regarding my child or me that have health or reproductive significance, and where prevention and/or treatment are available YES ☐ NO ☐
- I would like a karakia spoken over my and my child's blood samples before they are sent overseas YES ☐ NO ☐

- For any blood samples remaining in New Zealand I would like them: (Please tick which option applies)

  iv) Returned to me at the completion of the study ☐

  v) Disposed of with a karakia according to culturally appropriate laboratory protocol ☐

  OR

  vi) Disposed of according to standard laboratory protocol ☐

- I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant 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. YES ☐ NO ☐

- I wish to receive study updates over the course of the study period. YES ☐ NO ☐

- I wish to receive a summary of the results from the study. YES ☐ NO ☐

**Declaration by the Participant:**

Child's name: _____

Name of child's legal guardian: _____

Signature of child's legal guardian: _____

Date: _____

Contact phone number: _____

Contact email address: _____

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant and have answered all the participant's questions.

I believe that the participant's parent/guardian understands the study and has given informed consent to participate.

Researcher's name:_____

Signature: _____ Date: _____

# CONSENT FORM - Future Unspecified Research

## Maternal Psoriasis and Infant Neurodevelopmental Outcomes (MaPINO) Study

**Ethics Approval No.:**

**Coordinating Investigator:** Dr Hannah Jones, Paediatric Neurologist

**Please tick to indicate you consent to the following:**
*(If you need an interpreter, please tell us.)*

| | | |
|---|---|---|
| • I agree to the additional blood samples being collected from me and my baby and stored for possible future research related to the current research project, Maternal Psoriasis and Infant Neurodevelopmental Outcomes Study. | YES ☐ | NO ☐ |
| • I agree for my blood samples to be stored and used in future research of any type which has been properly approved. | YES ☐ | NO ☐ |
| • I wish to receive a copy of the results from any future research. | YES ☐ | NO ☐ |

**Declaration by the Participant:**

Child's name: _____

Name of child's legal guardian: _____

Signature of child's legal guardian: _____

Date: _____

Contact phone number: _____

Contact email address: _____

**Declaration by member of research team:**

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant and have answered all the participant's questions.

I believe that the participant's parent/guardian understands the study and has given informed consent to participate.

Researcher's name:_____

Signature: _____ Date: _____

# CONSENT FORM (Child) - Future Unspecified Research

## Maternal Psoriasis and Infant Neurodevelopmental Outcomes (MaPINO) Study

*(To be signed after delivery)*

**Ethics Approval No.:**

**Coordinating Investigator:** Dr Hannah Jones, Paediatric Neurologist

**Please tick to indicate you consent to the following:**
*(If you need an interpreter, please tell us.)*

| | | |
|---|---|---|
| • I agree to my child's blood sample being stored for possible future research related to the current research project, Maternal Psoriasis and Infant Neurodevelopmental Outcomes Study. | YES ☐ | NO ☐ |
| • I agree for my child's blood samples to be stored and used in future research of any type which has been properly approved. | YES ☐ | NO ☐ |
| • I wish to receive a copy of the results from any future research. | YES ☐ | NO ☐ |

**Declaration by the Participant:**

Child's name: _____

Name of child's legal guardian: _____

Signature of child's legal guardian: _____

Date: _____

Contact phone number: _____

Contact email address: _____

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant and have answered all the participant's questions.

I believe that the participant's parent/guardian understands the study and has given informed consent to participate.

Researcher's name:_____

Signature: _____ Date: _____