PARTICIPANT INFORMATION SHEET FOR FATHERS (Optional)

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

Ethics Approval No.: 2022 FULL 11776

Coordinating Investigator: Dr Hannah Jones, Paediatric Neurologist
Address: Paediatric Neuroservices, Starship Children's Health, Level 3, NZCR Building, 3 Ferncroft St, Grafton, Auckland 1142
Contact number: 09 307 4931

You are invited to take part in a research study with the mother of your child. Your participation in the study is entirely voluntary. This information sheet provides information about why we are doing the study, and what it would involve for you, your child's mother, and your child if you wish to take part. Please ask if there is anything that is not clear to you or if you would like more information. If you require an interpreter, we can organise one for you.

You may wish to discuss the study with a friend or whanau to help you decide whether you would like to participate or not. The research team are available to discuss the study with your whanau if you would like this.

Please indicate below if you would like to discuss the study through an interpreter:

English	I wish to have an interpreter	Yes	No
Deaf	I wish to have a New Zealand sign language interpreter	Yes	No
Māori	E hiahia ana ahau ki tetahi kaiwhaka Māori/kaiwhaka pakeha korero	Ae	Kao
Cook Island Māori	Ka inangaro au i tetai tangata uri reo	Ae	Kare
Fijian	Au gadreva me dua e vakadewa vosa vei au	Io	Sega
Niuean	Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu	E	Nakai
Samoan	Ou te mana'o ia i ai se fa'amatala upu	Ioe	Leai
Tokelaun	Ko au e fofou ki he tino ke fakaliliu te gagana Peletania ki na gagana o na motu o te Pahefika	Ioe	Leai
Tongan	Oku ou fiema'u ha fakatonulea	Io	Ikai

Once you understand the study and what is involved, if you would like to take part, please sign the consent form below. If you choose not to take part in the study, you do not need to give a reason, and your decision will not affect the care that your child's mother or your

child receives. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

Investigators

Dr Hannah Jones, Neurologist, Starship Hospital and Centre for Brain Research
A/Prof Jane Alsweiler, Neonatologist, Auckland City Hospital and University of Auckland
Dr Steven Lamb, Dermatologist, Auckland City Hospital and University of Auckland
Dr Paul Jarrett, Dermatologist, Counties Manukau District Health Board
Dr Michelle Wise, Obstetrician, Auckland City Hospital and University of Auckland
Dr Ngaire Anderson, Obstetrician, Waitemata District Health Board
Prof Russell Dale, Neurologist, The Children's Hospital at Westmead, University of Sydney

What is the purpose of the study?

Psoriasis is a common inflammatory skin condition that affects 1 – 2 % of people, and up to 10% of women have an autoimmune or inflammatory disease like psoriasis during pregnancy. The purpose of this study is to help us understand whether psoriasis and inflammation in pregnancy affects fetal brain development. Some animal models suggest inflammation in pregnancy influences brain development, but we do not know if this is the case in humans.

We will recruit 100 pregnant women with psoriasis and 100 pregnant women without psoriasis to the study and collect details regarding pregnancy and delivery. We will then assess each child's developmental profile when they are two years old.

Who can take part in this study?

Pregnant women with and without psoriasis. Participants must not have a diagnosis of any autoimmune disease.

The mother of your child has been recruited to the study as a pregnant woman with or without psoriasis. You are invited to also take part in the study by providing information regarding your medical history. Only biological fathers are eligible for this part of the study.

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

The study will involve:

1. Completing a study questionnaire
   We will ask you to please complete a 30-minute questionnaire which asks about your general health and wellbeing such as questions about mental health and education. We will ask you to please complete a similar questionnaire about your child and family's health and wellbeing when your child is two years old.

2. Accessing your medical records
   The research team may need to access your medical records clarify any data that is provided. We will review the mother of your child's medical records for details regarding her pregnancy and delivery as well as your child's medical records when they are two years old to collect data regarding their health.
3. A developmental assessment for your child
   We will arrange a one-hour developmental assessment when your child when he/she is two years old. The assessment is called the Bayley Scales of Infant and Toddler Development and will be performed by a child therapist or psychologist. We will provide you with a copy of the results of the developmental assessment, and if any areas of concern are raised, we will discuss these with you, inform your GP, and refer your child to your local paediatric service for further assessment and intervention if needed.

Where will this study be held?

If you agree to take part in the study, we will send the questionnaires electronically or by post to complete and return to us.

When your child is two years old, we will organise for him/her to have a developmental assessment at the University of Auckland, Grafton, Auckland. A travel allowance will be provided.

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.

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 study questionnaire asks general questions about anxiety, mood, and any history of trauma. The questionnaire will be coded for your privacy and support services are listed at the end of the questionnaire should you wish to seek support regarding any of the questions raised. The research team will review the answers of the questions and if they raise concern about your or your child's health, we will contact you to offer support and contact your general practitioner and/or a medical specialist as appropriate.

In a small proportion of children, the developmental assessment may detect unexpected developmental difficulties. This may be distressing for his or her parents, but an appropriately trained clinician will discuss these results with you, and we will refer the child

to the local paediatric service for further assessment and intervention if necessary. Early intervention has been shown to improve developmental outcomes so we expect this information will be helpful in the long-term.

What will happen to my child's and my information?

The data collected for the study will be stored against a unique study code. Only the research team will have access to data that identifies you. All study investigators have signed confidentiality agreements with their respective institutions.

Rarely, the research team may contact your general practitioner and/or a hospital specialist with your identifiable information if there is significant concern about your or your child's health and wellbeing.

Your child's developmental assessment is potentially useful information for his or her care, and we will make this available to your child's general practitioner or hospital specialist according to your preference indicated on the consent form below.

No material that could personally identify you will be used in any reports on this study.

How will my child's and my information be stored and what are the risks to my privacy?

Your child's identifiable developmental assessment will be held on Auckland District Health Board premises. After the study, it will be transferred to your child's medical records if you wish, or transferred to a secure archiving site and stored for at least 10 years after the youngest participant in the study turns 16 years. The data will then be destroyed.

Coded study data will be kept in a secure web application using a University of Auckland platform. The data platform complies with international and national regulatory requirements for electronic data capture systems.

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.

Cultural Statement

We recognise that knowledge is taonga and the research will be conducted in accordance with the principles of Māori data sovereignty.

Can I access my child and my information?

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

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).

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.

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.

Will I be informed of the results of the study?

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

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?

If you have further questions, concerns or complaints about the study at any stage, please contact the 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 - Control Group

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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 taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my child's medical care.
- I consent to the research staff collecting and processing information about my health.
- 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 or presentations on this study.
- If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw from the study may continue to be processed.
- I consent to the research team notifying my General Practitioner that I am participating in this

study.

- I am aware that the research team may contact General Practitioner and/or hospital specialist if the study data raises significant concerns about my health

- 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 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 ☐

- I consent to being contacted in the future to ask about participating in future studies related to this project YES ☐ NO ☐

Declaration by Father:

I hereby consent to taking part in this study.

Father's name: _____

Father'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: _____