



Queensland Family Cohort Study

PREGNANT PARTICIPANT Information and Consent Form

Scientific Title: Mater-Queensland Family Cohort: A snapshot of who we are now and a journey into the future

Mater Study Investigator/Coordinator	Participating Centres
<p>Chief Investigator Name: Prof Vicki Clifton Department: Pregnancy and Development Hospital / Site: Mater Research Institute Phone: 07 3443 7640 or 07 3163 8075 Email: vicki.clifton@mater.uq.edu.au</p> <p>Principal Investigator Name: Sailesh Kumar Department: Maternal Fetal Medicine Hospital / Site: Mater Mothers' Hospital Phone: 07 3163 8844 Email: sailesh.kumar@mater.uq.edu.au</p> <p>Principal Investigator Name: Assoc Prof Kym Rae Department: Pregnancy and Development Hospital / Site: Mater Research Institute Phone: 07 3443 7640 or 07 3163 8075 Email: kym.rae@mater.uq.edu.au</p> <p>Research Coordinator Name: Danielle Borg Department: Pregnancy and Development Hospital / Site: Mater Research Institute Daytime Phone: 07 3163 2571 Email: danielle.borg@mater.uq.edu.au</p>	<p>Coordinating Centre Mater Mother's Hospital Mater Research</p> <p>QLD Family Cohort Study Phone (Office Hours): 07 31635306 Email address: qldfamilycohort@mater.uq.edu.au</p> <p>Research Midwives Claire Thurston (Office Hours): 07 3163 5306 Email: claire.thurston@mater.uq.edu.au</p> <p>Study Phone: 0439 945 068</p> <p>MML Human Research Ethics Committee approval number: HREC/16/MHS/113</p>

WHAT IS QUEENSLAND FAMILY COHORT STUDY ?

You are invited to participate in the Queensland Family Cohort Study because you are recently pregnant and reside in Queensland. We hope to recruit 5000 pregnant people and their partners (if they have one) to participate in this study in 2022-2026.

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This study is being conducted by Professors Vicki Clifton, Sailesh Kumar, Kym Rae and their colleagues from the Mater Mothers' Hospital in Brisbane, with input from experts all across Queensland.

This Participant Information Sheet/Consent Form tells you about the research, and what is involved. Please read this information carefully. Please ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you must talk to your partner, if you have one, and you might want to talk about it with a relative, friend, your Doctor or Midwife.

WHY ARE WE DOING THIS STUDY?

Our long-term aim is to understand the health of Queensland people over the next few years and to see how the health of the family impacts on the health of pregnancies and the babies born. A very large number of participants are needed for this.

The study will also use the information to answer specific research questions being developed by our collaborating colleagues.

If you have a partner, then you both need to consent to the study for participation from 24 weeks to 6 weeks of birth. If one of you consents, but the other does not, neither of you will be able to take part.

For the child follow-up study, we require only the primary care giver at the time to consent to follow your child's development, health and well-being.

WHAT IS INVOLVED?

The information we would like to collect from you will come from answering questions about your physical and emotional well-being, what foods, drugs and supplements you take, information from your pregnancy record and about your birth. In our child follow-up survey, we are interested in hearing about your child's vaccinations, medical history, their developmental milestones and what food, medications and supplements your child might take.

WHAT WILL HAPPEN DURING THE STUDY?

1. You will be sent surveys to complete via email that you can complete at your leisure in your own home. These will arrive soon after enrolment, at 24 weeks, 28 weeks, and 36 weeks of pregnancy. We will also send surveys after the baby's due date to enable us to learn about your experiences and care during birth and also about your baby. When your baby is 6 weeks old there will be a further final survey about yourself and one about your baby's progress.
2. If you have told us you have a partner, they will be sent a consent form by email to sign. They will then receive surveys at the time of enrolment, when you are 24 weeks pregnant and when baby is 6 weeks old.
3. When your baby is 6 weeks old we will ask if you consent to taking part in the Child Health part of this study.
4. From 6 months of age and then every half a year until your child is 5 years old, we would like to collect survey and questionnaire data about your child's development, health, diet, medication, as well as the height and weight of the primary care giver and the child.
5. All parts of this study are conducted by email.

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TIMELINE OF STUDY PARTICIPATION – FOR YOU, YOUR PARTNER AND YOUR BABY.

We have set out the survey schedule for you, your partner, if you have one, and your baby in the Table below. The table below shows examples of what we ask about.

Survey Time Point	Survey Topics	Who is involved
Enrolment	Consent and medical history questionnaire; Housing; Employment; Sleep; Activity; Asthma	You Your Partner
24 Week	Medications; Health at 24 weeks; Dietary questionnaire; Emotional well-being; Sleep; Activity; Asthma; COVID-19 impact	You Your Partner
28 Week	Medications; Health at 28 weeks; Emotional well-being; Sleep; Activity; Asthma;	You
36 Week	Medications; Health at 36 weeks; Emotional well-being; Sleep; Activity; Asthma	You
Soon After Birth	Labour and birth details; Medications used; Baby's measurements, medications and feeding	You Baby
Six Weeks After Delivery	Medications; Your current health; Dietary questionnaire; Emotional well-being; Sleep; Activity; Asthma; COVID-19 impact	You Baby Your partner
Six Weeks After Delivery	Consent for QFC Child Health Study	Child's principal carer
From 2 months – 5 years of age for child	Questionnaires, height and weight recorded every 6 months. Development milestones; Child's diet; Child's activities;	Primary Care Giver Baby

During the current time of uncertainty around the COVID-19 pandemic, we are asking specific questions about the impact it has had on you. This includes any financial hardship it has imposed through travel or work restrictions. We do not share any information with the Australian Tax Office, Centrelink or any other agency that may be involved in your finances.

CHILD HEALTH FOLLOW-UP STUDY

We would like to understand from the primary care givers perspective, your child's development and health to understand potential drivers for disease risk and the influence of the environment on the health outcomes.

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The surveys and questionnaires below will be asked every 6 months as your child grows until 5 years of age.

Summary of Questionnaires:

Vaccination views and history

Medication, medication photos, recent medical history

Child development and movement

Child Eating

ANALYSIS OF THE QUESTIONNAIRES

The personal and health information that we collect in the study will come from the questionnaires. This information will form a “databank”.

The databank created in this study will be specifically for use in health and medical research and to advance our understanding of human health and disease.

All research material and information produced from databank analysis will be coded with a project specific number. The link to who you and your family are is kept separately and securely at Mater only. All data transfers will be safely encrypted. All research material will be stored in accordance with the Mater data storage policy.

Data will be analysed by researchers from the following institutions: The Mater Medical Research Institute, The Queensland University of Technology, The University of Queensland, Griffith University, QIMR Berghofer Medical Research Institute, The Australian Catholic University and James Cook University.

The research studies aiming to use the information collected will only be done after the individual research sub-studies have been developed in detail, and have approval from the relevant Human Research Ethics Committee (HREC). It may happen that expertise required for the sub-studies are outside the institutes listed above. These projects will still require approval by an HREC.

DATA LINKAGE

We would like to link the information you share with us to that held by Medicare, the Pharmaceutical Benefits Scheme (PBS) and QLD government databases. This helps us understand more about how your health and that of your family has been managed e.g. hospital admissions, prescriptions given.

WILL PARTICIPATION COST ANYTHING?

As participation in this study is voluntary, participants will not be paid. Completion of surveys requires access to the internet and a computer or smart phone.

POSSIBLE BENEFITS

You, your partner, and baby are not likely to benefit directly from your participation in this study. However, results from this study may have far-reaching positive implications for public

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health and how healthcare is offered in the future. Many people value their opportunity to contribute to their community in this way.

POSSIBLE RISKS

There are no risks identified with taking part, however there will be about 30mins needed to complete each survey.

YOUR RIGHTS

Participation in any research project is voluntary and you are free to withdraw from the study at any time. If you decide to withdraw, please let any member of the research team know.

All information gathered will be treated with confidence and no information that could identify you, your partner or your baby will be released to any person not associated directly with the study. These results may eventually be published in medical journals or at professional meetings, but you, your partner or your child will not be identified in any way.

Your information will remain confidential except in the case of a legal requirement to pass on personal information to authorised third parties. This requirement is standard and applies to information collected both in research and non-research situations. Such requests to access information are rare; however, we have an obligation to inform you of this possibility.

ANY QUESTIONS?

If at any time during the study you have any other queries, or immediate concerns please ring **0439 945 068** during office hours and one of our research team members will answer your call. If there is a medical emergency please call 000.

STUDY UPDATES

For more information about this study, please visit our website <https://qldfamilycohort.org>, Facebook page: <https://www.facebook.com/qldfc>, or Twitter account: <https://twitter.com/qldfamilycohort>.

Mater Hospital also has a Facebook account: <https://www.facebook.com/materqld>, and Mater Research has a Twitter account: <https://twitter.com/MaterResearch>, with information about this study and other studies being run currently at Mater Research.

STUDY APPROVAL

This study has been reviewed and approved by the Mater Misericordiae Limited Human Research Ethics Committee, and also by the Mater Governance Office. If you wish to discuss the approval process with someone not directly involved in the study, or have any concerns or complaints, you may contact the Human Research Ethics Committee office on: **(07) 3163 1585** or alternatively, the Mater Research Governance Officer on: **(07) 3163 3769**

WHAT DO I DO NEXT?

Please complete the questions on the electronic consent form, indicating you understand what the study involves and are happy to take part. We will then prepare your first survey.

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Queensland Family Cohort Study

PARTNER PARTICIPANT Information and Consent Form

Scientific Title: Mater-Queensland Family Cohort: A snapshot of who we are now and a journey into the future

Mater Study Investigator/Coordinator	Participating Centres
<p>Chief Investigator Name: Prof Vicki Clifton Department: Pregnancy and Development Hospital / Site: Mater Research Institute Phone: 07 3443 7640 or 07 3163 8075 Email: vicki.clifton@mater.uq.edu.au</p> <p>Principal Investigator Name: Sailesh Kumar Department: Maternal Fetal Medicine Hospital / Site: Mater Mothers' Hospital Phone: 07 3163 8844 Email: sailesh.kumar@mater.uq.edu.au</p> <p>Principal Investigator Name: Kym Rae Department: Pregnancy and Development Hospital / Site: Mater Mothers' Hospital Phone: Email: kym.rae@mater.uq.edu.au</p> <p>Research Coordinator Name: Danielle Borg Department: Pregnancy and Development Hospital / Site: Mater Research Institute Daytime Phone: 07 3163 2571 Email: danielle.borg@mater.uq.edu.au</p>	<p>Coordinating Centre Mater Mother's Hospital Mater Research</p> <p>QLD Family Cohort Study Phone (Office Hours): 07 3163 5306 Email address: qldfamilycohort@mater.uq.edu.au</p> <p>Research Midwives Claire Thurston (Office Hours): 07 3163 5306 Email: claire.thurston@mater.uq.edu.au</p> <p>Study Phone: 0439 945 068</p> <p>MML Human Research Ethics Committee approval number: HREC/16/MHS/113</p>

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This study is being conducted by Professors Vicki Clifton, Sailesh Kumar, and their colleagues from the Mater Mothers' Hospital in Brisbane, with input from experts all across Queensland.

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This Participant Information Sheet/Consent Form tells you about the research, and what is involved. Please read this information carefully. Please ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you must talk to your partner, and you might want to talk about it with a relative, friend, your Doctor or Midwife.

WHY ARE WE DOING THIS STUDY?

Our long-term aim is to understand the health of Queensland people over the next few years and compare it with the results of past studies. We wish to see how the health of the family impacts on the health of pregnancies and the babies born.

The study will also use the information to answer specific research questions being developed by our collaborating colleagues.

Both you and your partner need to consent to the study for participation from 24 weeks to 6 weeks of birth. If one of you consents, but the other does not, neither of you will be able to take part.

For the child follow-up study, we require only the primary care giver at the time to consent to follow your child's development, health and well-being.

WHAT IS INVOLVED?

The information we would like to collect from you will come from answering questions about your physical and mental health, what foods, drugs and supplements you take, information from your partner's pregnancy record and about birth. In our child follow-up survey, we are interested in hearing about your child's vaccinations, medical history, their developmental milestones and what food, medications and supplements your child might take.

WHAT WILL HAPPEN DURING THE STUDY?

1. You will be sent surveys to complete via email that you can complete at your leisure in your own home. These will arrive soon after enrolment, at 24 weeks and at 6 weeks after the birth of your child.
2. Your partner will receive surveys at enrolment, 24, 28 and 36 weeks of pregnancy, soon after birth and at 6 weeks after the birth.
3. When your baby is 6 weeks old we will ask if you consent to taking part in the Child Health part of this study.
4. From 6 months of age and then every half a year until your child is 5 years old, we would like to collect survey and questionnaire data about your child's development, health, diet, medication, as well as the height and weight of the primary care giver and the child.
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28 Week	Medications; Health at 28 weeks; Emotional well-being; Sleep; Activity; Asthma;	Your partner
36 Week	Medications; Health at 36 weeks; Emotional well-being; Sleep; Activity; Asthma	Your partner
Soon After Birth	Labour and birth details; Medications used; Baby's measurements, medications and feeding	Your partner Baby
Six Weeks After Delivery	Medications; Your current health; Dietary questionnaire; Emotional well-being; Sleep; Activity; Asthma; COVID impact	You Baby Your partner
Child Health Consent	Confirmation of consent to receive Child Health surveys	Primary care giver
From 2 months – 5 years of age for child	Questionnaires, height and weight recorded every 6 months. Development milestones; Child's diet; Child's activities;	Primary Care Giver Baby

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Child development and movement

Child Eating

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WILL PARTICIPATION COST ANYTHING?

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POSSIBLE BENEFITS

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POSSIBLE RISKS

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YOUR RIGHTS

Participation in any research project is voluntary and you are free to withdraw from the study at any time without affecting you, your pregnant partner's or your child's care in any way. If you decide to withdraw, please let any member of the research team know.

All information gathered will be treated with confidence and no information that could identify you, your partner or your baby will be released to any person not associated directly with the study. These results may eventually be published in medical journals or at professional meetings, but you, your partner or your child will not be identified in any way.

Your information will remain confidential except in the case of a legal requirement to pass on personal information to authorised third parties. This requirement is standard and applies to information collected both in research and non-research situations. Such requests to access information are rare; however, we have an obligation to inform you of this possibility.

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Mater Hospital also has a Facebook account: <https://www.facebook.com/materqld>, and Mater Research has a Twitter account: <https://twitter.com/MaterResearch>, with information about this study and other studies being run currently at Mater Research.

STUDY APPROVAL

This study has been reviewed and approved by the Mater Misericordiae Limited Human Research Ethics Committee (approval HREC/16/MHS/113), and also by the Mater Governance Office (approval RG-16-280). If you wish to discuss the approval process with someone not directly involved in the study, or have any concern or complaint, you may contact the Human Research Ethics Committee office on: **(07) 3163 1585** or alternatively, the Mater Research Governance Officer on: **(07) 3163 3769**.

WHAT DO I DO NEXT?

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