Document Title:	
Unit Record No.:	
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Given Names:	
DOB:	

The Mater-Queensland Family Cohort Pilot 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
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WHAT IS THE MATER-QUEENSLAND FAMILY COHORT PILOT?

You are invited to participate in the Mater-Queensland Family Cohort (MQFC) Pilot Study because you are recently pregnant and have chosen the Mater Mother's Hospital for delivery. We hope to recruit 400 pregnant people and their partners (if they have one) to participate in this pilot study in 2018-2020.

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.

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 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. A very large number of participants are needed for this. Before we undertake a large study, we must find out whether we can explain clearly what the research is about, and whether people are willing to undertake the activities requested in the study. We are therefore doing a small pilot study at Mater Mothers' Hospital before embarking on the larger study.

As well as finding out whether people are happy to be involved in this research, the pilot 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, collect information from the pregnancy record and also giving some biological samples such as saliva, blood, urine and stool (see below). We will perform additional ultrasounds to look at how your baby is growing. We will also request to take some samples from your baby after 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. At enrolment, we will answer any questions that you and your partner may have about the research, collect some information about you and your partner, including contact details, age, weight, height, education, occupation, ethnicity, country of origin, smoking status, general medical history. This can be completed over the phone or as an appointment onsite.
2. You will both be asked to attend a research visit at 24 weeks gestation. You may both attend the research visits at 28 and 36 weeks gestation, however attendance for partners is not required.
3. At the 24 week visit we will ask you both to fill out questionnaires. We would also like to measure your blood pressure, pulse, height and weight, and take some biological samples from you both.
4. Following the birth of your baby, details of your pregnancy, birth, and baby will be collected from your and your baby's medical records while you are in hospital, and samples will be

taken at delivery (placenta) and while you are at hospital. Samples will also be requested 6 weeks postnatally from you and your baby.

5. From 2 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, diet, medication, as well as the height and weight of the primary care giver and the child. No biological samples will be taken at this time.

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

We have set out all the visits and tests for you, your partner, if you have one, and your baby in the Table below. The time your appointment will take is between 30 and 90 minutes if your questionnaire has been completed beforehand.

Time Point	Duration of Visit (Mins)	Visit Comprised Of	Who is involved
Enrolment	30-60	Consent and medical history questionnaire- face to face or telephone appointment	You Your Partner
24 Week	45-90	Ultrasound, questionnaire and biological samples collected	You Your Partner
28 Week	45-90	Ultrasound, questionnaire and biological samples collected	You
36 Week	45-90	Ultrasound, questionnaire and biological samples collected, Cosinuss One ear device given (to measure heart rate and body temperature).	You
Delivery / On Ward	30	Chart review, questionnaire and biological samples collected	You after delivery Baby
Six Weeks After Delivery	30-60	Questionnaire and biological samples collected	You Baby
From 2 months – 5 years of age for child	30 min online	Questionnaires, height and weight recorded	Primary Care Giver Baby

CLINICAL AND BIOLOGICAL SAMPLES

Weight/Clinical Measurements: During the study we would like to measure your blood pressure, height, weight, body mass index, waist circumference, skin fold thickness and body composition.

Biological Samples: We would also like to collect a variety of biological samples (listed below). These will be used in smaller sub-studies most of which have not yet been fully defined. Broadly, the samples will be tested for bacteria, the microbiome of skin and intestines will be observed and factors produced by the body (markers) which could be associated with

variations in physical or mental health, allergies, pregnancy-related conditions, or the development of illnesses may be looked at by researchers.

The tests include examining genes, which are made up of DNA – the chemical structure carrying your genetic information. Genes are inherited from your parents and determine characteristics such as the colour of your eyes or hair. While genetic testing will be performed on yours, your baby's and your partner's samples, no paternity tests will be performed.

By using both the questionnaire information and the biological samples, we may be able to understand more about the influence of the environment and health behaviours on well-being or the development of illness. We are also interested in discovering why some people could experience a side effect to a treatment and others do not.

Your partner will have similar questionnaires and samples taken, and we also hope to collect samples from your baby after birth. A brief explanation of the tests that will be taken from you is given below.

Blood Samples: will be collected to separate red blood cells, plasma and cells from your immune system and used to measure circulating markers and test immune function.

Breast Milk Sample: will be used to look at the natural nutrients and other compounds found in breast milk/colostrum and the natural bacteria that live on the skin of your breast and in breast milk/colostrum.

Cheek Swab and Saliva Samples: will collect both your DNA and the natural bacteria and enzymes in your mouth. Your DNA will tell us about your immune system and how this relates to allergies and disease.

Hair Samples: will be used to screen for minerals and environmental toxins.

Placenta: placenta will be used to look at proteins and DNA that you share with your baby, energy consumption, and look at the natural bacteria that live on the outside of the placenta.

Skin Swabs: will be used to look at the natural bacteria that live on your skin. A skin swab will be taken from your chest.

Stool Samples and/or Swabs: will be used to look at the natural bacteria that live in your gut.

Toenail Samples: will be used as a toxicology screen.

Ultrasound Scans: will be performed at all research visits from 24 weeks. These scans do not involve x-ray or other radiation. These scans will be used to look at the growth and development of your baby.

Urine Samples: will be used to look at the natural bacteria that live in the urinary tract, measure kidney function and as a toxicology screen.

Vaginal Swabs: self-administered vaginal swab will be taken at 24 and 36 weeks gestation to look at the natural bacteria that live in your vagina. The balance of bacteria in your vaginal tract may change throughout your pregnancy so it is important to get the two samples. We will tell you how to take the swab and give you instructions.

Ear Device: A subset of individuals who would like to participate in an additional measure will be given a small in-ear device to take home from 36 weeks gestation until the end of pregnancy. The device measures heart rate and body temperature. These measurements will be compared with data collected about your baby after birth.

We will use this information to investigate if measuring maternal heart rate and body temperature is a useful tool for monitoring babies health and development in the future.

Your Partner

We will also ask your partner if we may collect information and biological samples from them as for you. Please discuss this with each other to ensure you both feel comfortable with the samples that we are requesting.

Your Baby

For infants, measures include weight, body length, head, upper arm and abdominal circumference. In addition, we would like to perform a Pea Pod scan on your baby while on the postnatal ward, and at the six week follow up research visit. The Pea Pod measures the ratio of fat in the body. The Pea Pod measurement will happen when the baby is settled and will take approximately 30 mins. The measurement works on air displacement and will not hurt your baby at all. Both you and your partner can attend the scan.

After birth, a blood sample will also be collected from your baby via a tiny prick in the heel. The neonatal screen is part of routine clinical care, with a small spot of baby's blood collected onto a piece of paper (Neonatal Screen card). We would like your permission to collect a second spot of blood on another card, just for this research, at the same time as the usual neonatal screen.

Placental Sample: will be used to look at the blood vessels, structure and growth of your placenta to see how it has grown during the development of your baby. Photos, and several small tissue samples will be collected from the placenta just after your baby's birth. This will not hurt your baby and is taken after the placenta is delivered and the baby is no longer attached.

Cord Blood: will be taken just after you give birth. This will not hurt your baby and is taken from the cord, once the placenta is delivered and the baby is no longer attached. If you would like to donate your cord blood to the cord blood bank, or keep the cord blood for your own uses, you can still be a part of this study. However, you must make this known to your research staff member to ensure we handle your placenta accordingly.

Other Biological Samples: We will ask if we can take a skin swab and saliva sample from your baby after birth, and collect a cheek swab, urine and stool sample from your baby on the postnatal ward, and again at 6 weeks after birth. If possible, a hair and toe nail sample will be taken from your baby at six weeks of age.

Summary of Biological Samples

Your Samples													
Time Point / Sample	Blood Sample	Breast Milk Sample	Cheek Swab	Hair Sample	Placenta Sample	Saliva Sample	Skin Swab	Stool Sample	Toenail Sample	Ultrasound Scan	Urine Sample	Vaginal Swab	Weight Measures
Enrolment													✓
24 Weeks	✓		✓	✓		✓	✓	✓	✓	✓	✓	✓	✓
28 Weeks	✓					✓		✓		✓	✓		✓
36 Weeks	✓		✓			✓				✓	✓	✓	✓
Delivery / On Ward		✓			✓								
Six Weeks After Delivery	✓	✓	✓	✓		✓	✓	✓	✓		✓		✓

Baby's Samples										
Time Point / Sample	Blood Spot	Cheek Swab	Cord Blood	Hair Sample	Saliva Sample	Skin Swab	Stool Sample	Toenail Sample	Urine Sample	Weight Measures
Delivery / On Ward	✓	✓	✓			✓	✓		✓	✓
Six Weeks After Delivery		✓		✓	✓		✓	✓	✓	✓

OPT IN AND OPT OUT MEASURES

We will also be asking you if you would like to participate in some additional measures. You can choose to opt in or opt out of these measures.

Photo/short video:

We would like to take a photo or short video of how your baby's mouth latches during early breastfeeding. Your face will not be shown in this photo or clip, and it will be reviewed by lactation consultants and nutritionists. We will ask if you consent to this in the consent form.

Ear Device:

We would like to invite a subgroup of individuals to participate in an additional part of our study where we measure heart rate and body temperature during pregnancy. To do this, we have specialised ear devices that fit discretely into the ear (similar to an over-ear headphone). The device doesn't hurt but may feel uncomfortable.

We will invite participants to wear this ear device from 36 weeks gestation until the end of pregnancy. We will ask that you wear the device during the day, at times of rest and times of

activity (for example, while sitting and watching TV and while going for an afternoon walk etc.). The time and duration that you wear the device is up to you.

The ear device is linked to a mobile phone application available on the Google play store. We will ask if you consent to this opt-in measure in the consent form.

MODIFIED TIMELINE AND SAMPLES DURING AN INFECTIOUS PANDEMIC

During a time of isolation due to an infectious pandemic such as the coronavirus (COVID-19), we require to change how we collect samples to ensure the safety of you, your partner and your baby.

Instead of face to face appointments with our research staff, you and your partner will receive a telehealth appointment at the same time points listed above in the table. Unfortunately, this means that the ultrasounds cannot be performed, due to social distancing rules dictated by the federal government.

Instead of the biological sample collection done by your research staff at your appointment time, we will post you a kit with step by step instructions on how to collect some of your own samples. We will include an express envelope for you to send your samples back for processing.

Below is a summary of the type of biological samples we will ask you or your birthing midwife to take:

Time Point / Sample	Cheek Swab	Hair Sample	Placenta Sample	Saliva Sample	Skin Swab	Stool Sample*	Toenail Sample	Vaginal Swab	Weight Measures
Enrolment									✓
24 Weeks	✓	✓		✓	✓	✓	✓	✓	✓
28 Weeks				✓		✓			✓
36 Weeks	✓			✓				✓	✓
Delivery / On Ward			✓						
Six Weeks After Delivery	✓	✓		✓	✓	✓	✓		✓

***** Your stool sample will be in the form of a microba swab taken from the smear of stool on the toilet paper you used.

Placenta sampling will be done by the birthsuite midwives at hospital.

During a time of limited social interaction like that of COVID-19, we want to check in on you to ensure you and your family are travelling ok. We will ask you to fill out a questionnaire specifically about your interaction with COVID-19, if you had any cold symptoms, how your mental health is going and if you have experienced any financial hardship because of the restrictions the pandemic has placed on you and your family. At subsequent appointments

throughout your partner's pregnancy (24-, 28-, 36-weeks' gestation and 6 weeks post-partum), we will check in to see whether anything has changed for you by sending out the questionnaire again. Please remember, none of the information you divulge will be shared with any governing body such as Centrelink, the Australian Taxation Office or any other financial institution.

Your Partner

We will also ask your partner if we may collect information and biological samples from them as for you. Please discuss this with each other to ensure you both feel comfortable with the samples that we are requesting in this modified version of the study.

Your Baby

During this time of limited social interaction, we will no longer use the PeaPod to obtain body composition measurements.

Measurements for your infant will be taken from your infant's red book, your child's medical record and from your records if you see your GP, paediatrician, or child health nurse.

We would like your birthing midwife to get a few photos and a sample of your placenta. We will send you a placenta kit that has detailed instructions and diagrams that can be handed to your midwife of how to do these. If your birthing midwife is unable to, and if your partner can, we will ask that your partner take the photos of your partner's placenta to send to us.

We will also ask the midwife to take a small sample of blood from the cord to be placed onto a neonatal screening card and left at the delivery suite to be collected by our staff.

On the postnatal ward and again at 6 weeks of age, we would like you, or your partner, to collect a urine sample, a skin swab, a cheek swab and a stool microba swab from your baby. If possible, hair and toenail samples can be collected at these times too.

Below is a summary of the type of biological samples we will ask you, your partner or your birthing midwife to take from your baby:

Time Point / Sample	Blood Spot	Cord Blood	Hair Sample	Saliva Sample	Skin Swab	Stool Sample*	Toenail Sample	Urine Sample	Weight Measures
Delivery / On Ward	✓	✓			✓	✓		✓	✓
Six Weeks After Delivery			✓	✓	✓	✓	✓	✓	✓

***** Your baby's stool sample will be in the form of a microba swab taken from the smear of stool from their nappy.

We will still ask if you would like to opt in or opt out of the additional photo/short video and ear device measures.

REMOTE CHILD 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.

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, BIOLOGICAL SAMPLES, MEASUREMENTS AND GENETIC INFORMATION

The biological samples collected during the pilot study will form a "biobank". A biobank is a large collection of human biological materials (biospecimens) that is linked to relevant personal and health information.

The personal and health information that we collect in the pilot study will come from the questionnaires, recorded measures, genetic information and medical chart reviews. This information will form a "databank".

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

Information collected from the child follow up survey will be linked to the QFC Pilot Study databank.

All research material and information produced from biobank and 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.

Biospecimens and 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 biospecimens and 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. It may happen that expertise required for the sub-studies are outside the institutes listed above. These projects will still require approval by a HREC.

It also may happen that results from the research analyses could produce an important clinical finding that represents a major risk or benefit to you, your blood relatives' or your community's

health. If there is something that can be done about it or it can be monitored over time it is advisable that we tell you about this. You can choose not to be contacted, but otherwise, a member of the Mater QFC team will contact you initially via letter, and then by telephone. We will ask if you consent to this and for contact details on the consent form.

WILL PARTICIPATION COST ME?

As participation in this study is voluntary, participants will not be paid, however we will provide either a parking voucher or grocery gift card if you complete the surveys and supply the samples to a maximum of 5 per family. The child follow-up study all occurs remotely and only requires access to the internet.

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 health and how healthcare is offered in the future. You and your family may enjoy the one-to-one research support contact and additional ultrasound scans taken throughout the study, which will enable you to see your growing baby more regularly than during your routine antenatal care.

POSSIBLE RISKS

There are few risks to being involved. Taking blood may cause brief discomfort or pain. All blood samples will be taken by trained, experienced staff to minimise any discomfort. The collection of other samples may feel strange but should not hurt. Participation in the study does take up time however, with time spent on answering questionnaires and having samples taken. Understanding whether involvement is an acceptable burden is an important question we hope to answer in this pilot study.

ALTERNATE CONTACTS

We would like you to provide us with the name and contact details of a person who may be contacted if any extra support is required. This person could be a close family member or friend who is not your partner. We may also need to use your alternate contact if we are unable to contact you or your partner (e.g. if you have moved/changed numbers and overlooked informing us). If we need to use your alternate contact we would explain who we are, and that you are involved in a study and have given us their details as alternate contact. No other personal details will be discussed.

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 pregnancy, your 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.

ANY QUESTIONS?

If at any time during the study you have any problems regarding appointments or have any other queries, or immediate concerns please ring **0439 945 068** 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.

The Mater also has a Facebook page: 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.

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**

CONSENT FORM

Title	Mater-Queensland Family Cohort: A snapshot of who we are now and a journey into the future
Short Title	Mater-Queensland Family Cohort (MQFC)
Protocol Number	*HREC/16/MHS/113*
Coordinating Principal Investigator/ Principal Investigator	*Prof. Vicki Clifton, Prof. Sailesh Kumar*
Associate Investigator(s)	*A/Prof Kym Rae, Dr Danielle Borg, Ms Claire Thurston, Mrs Loretta Weatherall, Dr Davide Fontanarosa, Dr Cameron Hurst*
Location	*Mater Mother's Hospital, Mater Research*

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I understand that in an event of an infectious pandemic, like COVID-19, the study will use a modified version of the study, to ensure the safety of my family and the study staff.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I understand that biospecimens collected will form a biobank, which will be linked to the databank of information collected about me which includes measures taken, questionnaires, genetic information and medical chart information. I understand that the biobank and databank will be used by collaborating researchers in sub-studies as described in the information sheet. These studies will be approved by an appropriate Human Research Ethics Committee before they can proceed.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my or my child's future health care.

I understand that I will be given a signed copy of this document to keep.

With respect to additional opt out and opt in measures:

a. I wish to participate in the additional measure of a photo or short video that captures how my baby's mouth latches during early breast feeding. Yes ☐ No ☐

b. I wish to participate in the additional measures of heart rate and body temperature using the Cosinuss One ear device as described in the information sheet. Yes ☐ No ☐

With respect to receiving information in relation to my biological samples:
If research with my DNA and/biological samples reveals some other medical condition relating to me or my family, for which treatment is available or monitoring of the condition should occur:

a. I wish to be informed Yes ☐ No ☐

b. I wish for affected family members to be informed and I give my consent for the researcher to approach my relatives on my behalf. Yes ☐ No ☐

With respect to the child follow-up survey:
I understand that my child's health and development information will be linked to the databank from the Mater QLD Family Cohort.

I understand that any further research studies wanting to use databank data will be deidentified and will require approval from an appropriate Human Research Ethics Committee before they can proceed.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Research Staff†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Research Staff† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature (DATE DD/MM/YYYY).

Document Title:	
Unit Record No.:	
Surname:	
Given Names:	
DOB:	

The Mater-Queensland Family Cohort Pilot 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
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 **Principal Investigator** Name: Prof Sailesh Kumar Department: Maternal Fetal Medicine Hospital / Site: Mater Mothers' Hospital Phone: 07 3163 8844 Email: sailesh.kumar@mater.uq.edu.au **Research Coordinator** Name: Dr Danielle Borg Department: Pregnancy and Development Hospital / Site: Mater Research Institute Daytime Phone: 07 3163 2571 Email: danielle.borg@mater.uq.edu.au	**Coordinating Centre** Mater Mother's Hospital Mater Research QLD Family Cohort Study Phone (Office Hours): 07 3163 2571 Email address: qldfamilycohort@mater.uq.edu.au **Research Midwives** Claire Thurston (Office Hours): 07 3163 5306 **Indigenous Research Assistant** Loretta Weatherall (Office Hours): 07 3163 8068 Study Phone: **0439 945 068**

WHAT IS THE MATER-QUEENSLAND FAMILY COHORT PILOT?

You are invited to participate in the Mater-Queensland Family Cohort (MQFC) Pilot Study because you and your partner are expecting a baby and have chosen the Mater Mother's Hospital for delivery. We hope to recruit 200 pregnant people and their partners (if they have one) to participate in this pilot study in 2018 - 2020

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.

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. A very large number of participants are needed for this. Before we undertake a large study, we must find out whether we can explain clearly what the research is about, and whether people are willing to undertake the activities requested in the study. We are therefore doing a small pilot study at Mater Mothers' Hospital before embarking on the larger study.

As well as finding out whether people are happy to be involved in this research, the pilot 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, and also giving some biological samples (such as saliva, blood, urine and stool). We will ask the same of your partner, collect information from the pregnancy record, and undertake some other tests such as additional ultrasounds (see below). We will also request to take some samples from your baby after birth.

WHAT WILL HAPPEN DURING THE STUDY?

1. At enrolment, we will answer any questions that you and your partner may have about the research, collect some information about you and your pregnant partner, including contact details, age, weight, height, education, occupation, ethnicity, country of origin, smoking status, general medical history. This can be completed over the phone or as an appointment onsite.
2. You will both be asked to attend a research visit at 24 weeks gestation. You may both attend the research visits at 28 and 36 weeks gestation, however attendance for partners is not required.
3. At the 24 week visit we will ask you both to fill out questionnaires. We would also like to measure your blood pressure, pulse, height and weight, and take some biological samples from you both.
4. Following the birth of your baby, details of your partner's pregnancy, birth, and baby will be collected from your partner's and baby's medical records while they are in hospital, and samples will be taken at delivery (placenta) and while you are at hospital. Samples will also be requested 6 weeks postnatally from your partner and baby.
5. From 2 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, diet, medication, as well as the height and weight of the primary care giver and the child. No biological samples will be taken at this time.

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

We have set out all the visits and tests for you, your partner and your baby in the Table below. The time your appointment will take is between 30 and 90 minutes if your questionnaire has been completed beforehand.

Time Point	Duration of Visit (Mins)	Visit Comprised Of	Who is involved
Enrolment	30-60	Consent and medical history questionnaire- face to face or telephone appointment	Pregnant partner **You**
24 Week	45-90	Ultrasound, questionnaire and biological samples collected	Pregnant partner **You**
28 Week	45-90	Ultrasound, questionnaire and biological samples collected	Pregnant partner
36 Week	45-90	Ultrasound, questionnaire and biological samples collected, Cosinuss One ear device given (to measure heart rate and body temperature).	Pregnant partner
Delivery / On Ward	30	Chart review, questionnaire and biological samples collected	Partner after delivery Baby
Six Weeks After Delivery	30-60	Questionnaire and biological samples collected	Partner Baby
From 2 months – 5 years of age for child	30 min online	Questionnaires, height and weight recorded	Primary Care Giver Baby

CLINICAL AND BIOLOGICAL SAMPLES

Weight/Clinical Measurements: starting when your pregnant partner reaches 24 weeks gestation, we would like to measure your blood pressure, height, weight, body mass index, waist circumference, skin fold thickness and body composition.

Biological Samples: We would also like to collect a variety of biological samples (listed below). These will be used in smaller sub-studies most of which have not yet been fully defined. Broadly, the samples will be tested for bacteria, the microbiome of skin and intestines will be observed and factors produced by the body (markers) which could be associated with variations in physical or mental health, allergies, pregnancy-related conditions, or the development of illnesses may be looked at by researchers.

The tests include examining genes, which are made up of DNA – the chemical structure carrying your genetic information. Genes are inherited from your parents and determine characteristics such as the colour of your eyes or hair. While genetic testing will be performed on the mother's, baby's and partner's samples, no paternity tests will be performed.

By using both the questionnaire information and the biological samples, we may be able to understand more about the influence of the environment and health behaviours on well-being

or the development of illness. We are also interested in discovering why some people could experience a side effect to a treatment and others do not.

Your partner will have similar questionnaires and samples taken, however we hope to collect some additional samples from your partner, as well as samples from your baby after birth. A brief explanation of the tests that will be taken from you at the 24 week visit is given below.

Blood Samples: will be collected to separate red blood cells, plasma and cells from your immune system and used to measure circulating markers and test immune function.

Cheek Swab and Saliva Samples: will collect both your DNA and the natural bacteria and enzymes in your mouth. Your DNA will tell us about your immune system and how this relates to allergies and disease.

Hair Samples: will be used to screen for minerals and environmental toxins.

Toenail Samples: will be used as a toxicology screen.

Skin Swabs: will be used to look at the natural bacteria that live on your skin. A skin swab will be taken from your chest.

Urine Samples: will be used to look at the natural bacteria that live in the urinary tract, measure kidney function and as a toxicology screen.

Stool Samples: will be used to look at the natural bacteria that live in your gut.

Your Pregnant Partner

We will also ask your pregnant partner if we may collect information and biological samples from them as for you, with some additional tests like ultrasound scans, placenta, breast milk and vaginal swabs. Please discuss this with each other to ensure you both feel comfortable with the samples that we are requesting.

Your Baby

For infants, measures include weight, body length, head, upper arm and abdominal circumference. In addition, we would like to perform a Pea Pod scan on your baby while on the postnatal ward, and at the six week follow up research visit. The Pea Pod measures the ratio of fat in the body. The Pea Pod measurement will happen when the baby is settled and will take approximately 30 mins. The measurement works on air displacement and will not hurt your baby at all. Both you and your partner can attend the scan.

We will also be collecting the placenta and cord blood. This will be taken after birth when the baby is no longer attached. This will not hurt your baby.

After birth, a blood sample will also be collected from your baby via a tiny prick in the heel. The neonatal screen is part of routine clinical care, with a small spot of baby's blood collected onto a piece of paper (Neonatal Screen Card). We would like your permission to collect a second spot of blood on another card, just for this research, at the same time as the usual neonatal screen.

We will ask if we can take a skin swab and saliva sample from your baby after birth, and collect a cheek swab, urine and stool sample from your baby on the postnatal ward, and again at 6

weeks after birth. If possible, a hair and toenail sample will be taken from your baby at six weeks of age.

Summary of Biological Samples

Your Samples									
Time Point / Sample	Blood Sample	Cheek Swab	Hair Sample	Saliva Sample	Skin Swab	Stool Sample	Toenail Sample	Urine Sample	Weight Measures
Enrolment									✓
24 Weeks	✓	✓	✓	✓	✓	✓	✓	✓	✓

Baby's Samples										
Time Point / Sample	Blood Spot	Cheek Swab	Cord Blood	Hair Sample	Saliva Sample	Skin Swab	Stool Sample	Toenail Sample	Urine Sample	Weight Measures
Delivery / On Ward	✓	✓	✓			✓	✓		✓	✓
Six Weeks After Delivery		✓		✓	✓		✓	✓	✓	✓

MODIFIED TIMELINE AND SAMPLES DURING AN INFECTIOUS PANDEMIC

During a time of isolation due to an infectious pandemic such as the coronavirus (COVID-19), we require to change how we collect samples to ensure the safety of you, your pregnant partner and your baby.

Instead of face to face appointments with our research staff, you and your partner will receive a telehealth appointment at the same time points listed above in the table. Unfortunately, this means that the ultrasounds cannot be performed, due to social distancing rules dictated by the federal government.

Instead of the biological sample collection done by your research staff at your appointment time, we will post you a kit with step by step instructions on how to collect some of your own samples. We will include an express envelope for you to send your samples back for processing.

Below is a summary of the type of biological samples we will ask you to take in the comfort of your own home:

Time Point / Sample	Cheek Swab	Hair Sample	Saliva Sample	Skin Swab	Stool Sample*	Toenail Sample	Weight Measures
Enrolment							✓
24 Weeks	✓	✓	✓	✓	✓	✓	✓

***** Your stool sample will be in the form of a microba swab taken from the smear of stool on the toilet paper you used.

During a time of limited social interaction like that of COVID-19, we want to check in on you to ensure you and your family are travelling ok. We will ask you to fill out a questionnaire specifically about your interaction with COVID-19, if you had any cold symptoms, how your mental health is going and if you have experienced any financial hardship because of the restrictions the pandemic has placed on you and your family. At subsequent appointments throughout your partner's pregnancy (24-, 28-, 36-weeks' gestation and 6 weeks post-partum), we will check in to see whether anything has changed for you by sending out the questionnaire again. Please remember, none of the information you divulge will be shared with any governing body such as Centrelink, the Australian Taxation Office or any other financial institution.

Your Pregnant Partner

Your pregnant partner will no longer have ultrasounds, placenta sampling will be done by midwives and will not be asked to send a sample of breast milk.

Your Baby

During this time of limited social interaction, we will no longer use the PeaPod to obtain body composition measurements.

Measurements for your infant will be taken from your infant's red book, your child's medical record and from your records if you see your GP, paediatrician, or child health nurse.

We would like your birthing midwife to get a few photos and a sample of your partner's placenta. We will send you a placenta kit that has detailed instructions and diagrams that can be handed to your midwife of how to do these. If your birthing midwife is unable to, and if you can, we ask that you take the photos of your partner's placenta to send to us.

We will also ask the midwife to take a small sample of blood from the cord to be placed onto a neonatal screening card and left at the delivery suite to be collected by our staff.

On the postnatal ward and again at 6 weeks of age, we would like you, or your partner, to collect a urine sample, a skin swab, a cheek swab and a stool microba swab from your baby. If possible, hair and toenail samples can be collected at these times too.

Below is a summary of the type of biological samples we will ask you, your partner or your birthing midwife to take from your baby:

Time Point / Sample	Blood Spot	Cord Blood	Hair Sample	Saliva Sample	Skin Swab	Stool Sample*	Toenail Sample	Urine Sample	Weight Measures
Delivery / On Ward	✓	✓			✓	✓		✓	✓
Six Weeks After Delivery			✓	✓	✓	✓	✓	✓	✓

***** Your baby's stool sample will be in the form of a microba swab taken from the smear of stool from their nappy.

REMOTE CHILD 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.

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, BIOLOGICAL SAMPLES, MEASUREMENTS AND GENETIC INFORMATION

The biological samples collected during the pilot study will form a "biobank". A biobank is a large collection of human biological materials (biospecimens) that is linked to relevant personal and health information.

The personal and health information that we collect in the pilot study will come from the questionnaires, recorded measures, genetic information and medical chart reviews. This information will form a "databank".

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

Information collected from the child follow up survey will be linked to the QFC Pilot Study databank.

All research material and information produced from biobank and 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.

Biospecimens and data will then 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 biospecimens and 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 (MML HREC Number EC 00332).

It may happen that expertise required for the sub-studies are outside the institutes listed above. These projects will still require approval by a HREC.

It also may happen that results from the research analyses could produce an important clinical finding that represents a major risk or benefit to you, your blood relatives' or your community's health. If there is something that can be done about it or it can be monitored over time it is advisable to tell you about this. You will only be notified of individual results if this is so. You can choose not to be contacted, but otherwise, a member of the Mater QFC team will contact you initially via letter, and then by telephone. We will ask if you consent to this and for contact details on the consent form.

WILL PARTICIPATION COST ME?

As participation in this study is voluntary, participants will not be paid, however we will provide either a parking voucher or a grocery gift card if you complete the surveys and supply the samples to a maximum of 5 per family. The child follow-up study all occurs remotely and only requires access to the internet.

POSSIBLE BENEFITS

You, your pregnant 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 health and how healthcare is offered in the future. You and your family may enjoy the one-to-one research support contact and additional ultrasound scans taken throughout the study, which will enable you to see your growing baby more regularly than during your routine antenatal care.

POSSIBLE RISKS

There are few risks to being involved. Taking blood may cause brief discomfort or pain. All blood samples will be taken by trained, experienced staff to minimise any discomfort. The collection of other samples may feel strange but should not hurt. Participation in the study does take up time however, with time spent on answering questionnaires and having samples taken. Understanding whether involvement is an acceptable burden is an important question we hope to answer in this pilot study.

ALTERNATE CONTACTS

We would like you to provide us with the name and contact details of a person who may be contacted if any extra support is required. This person could be a close family member or friend who is not your partner. We may also need to use your alternate contact if we are unable to contact you or your partner (e.g. if you have moved/changed numbers and overlooked informing us). If we need to use your alternate contact we would explain who we are, and that you are involved in a study and have given us their details as alternate contact. No other personal details will be discussed.

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.

ANY QUESTIONS?

If at any time during the study you have any problems regarding appointments or have any other queries, or immediate concerns please ring **0439 945 068** 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.

The Mater also has a Facebook page: 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.

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 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.**

CONSENT FORM

Title	Mater-Queensland Family Cohort: A snapshot of who we are now and a journey into the future
Short Title	Mater-Queensland Family Cohort (MQFC)
Protocol Number	*HREC/16/MHS/113*
Coordinating Principal Investigator/ Principal Investigator	*Prof. Vicki Clifton, Prof. Sailesh Kumar*
Associate Investigator(s)	*A/Prof Kym Rae, Dr Danielle Borg, Ms Claire Thurston, Mrs Loretta Weatherall, Dr Davide Fontanarosa, Dr Cameron Hurst*
Location	*Mater Mother's Hospital, Mater Research*

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I understand that in an event of an infectious pandemic, like COVID-19, the study will use a modified version of the study, to ensure the safety of my family and the study staff.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I understand that biospecimens collected will form a biobank, which will be linked to the databank of information collected about which includes measures taken, questionnaires, genetic information and medical chart information. I understand that the biobank and databank will be used by collaborating researchers in sub-studies as described in the information sheet. These studies will be approved by an appropriate Human Research Ethics Committee before they can proceed.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my or my child's future health care.

I understand that I will be given a signed copy of this document to keep

With respect to receiving information in relation to my biological samples:
If research with my DNA and/biological samples reveals some other medical condition relating to me or my family, for which treatment is available or monitoring of the condition should occur:

a. I wish to be informed Yes ☐ No ☐

b. I wish for affected family members to be informed and I give my consent for the researcher to approach my relatives on my behalf. Yes ☐ No ☐

With respect to the child follow-up survey:
I understand that my child's health and development information will be linked to the databank from the Mater QLD Family Cohort.

I understand that any further research studies wanting to use databank data will be deidentified and will require approval from an appropriate Human Research Ethics Committee before they can proceed.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Research Staff†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Research Staff† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project. Note: All parties signing the consent section must date their own signature. (DATE DD/MM/YYYY).