Newcastle 1000 Pilot Study

Paternal Participant Information and Consent Form

Invitation

You are invited to participate in the Newcastle 1000 Pilot Study. This study is being conducted by Professor Craig Pennell, Chair in Obstetrics and Gynaecology at the University of Newcastle and Professor of Maternal Fetal Medicine at the John Hunter Hospital.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. 'What is the purpose of this study?'

We know that the first 1000 days of life is an important time for babies to develop and grow. Our long term aim is to understand how the health of a baby's parents and a child's first two years of life can impact their development and growth. We will need a lot of families to be able to do this, so before we can undertake such a large study we need to do a smaller study (called a pilot study) to make sure families are happy with how we explain the study, how we invite them into the study, and what we are asking them to do.

2. 'Why have I been invited to participate in this study?'

This study is suitable for you if you have a partner who is pregnant, between 11 – 14 weeks gestation, and you are planning ot have the baby in Newcastle or the surrounding area.

3. 'Are there any reasons why this study may not be suitable for me?"

If you and your partner are not planning to stay in the Newcastle or Hunter New England area after the birth of your baby this study may not be suitable for you. Ideally we would like families to be planning to stay in the area so we can contact you to see how you and your baby are going after your birth.

4. 'What does this study involve?'

If you agree to participate in this study, you will be asked to sign the Participant Consent Form. At the moment we are asking you to be in the pilot study which involves four visits through out your pregnancy and two check ups with your baby when they are six weeks and six months old. We would like to follow up your child's health and may contact you after the pilot study to ask if you would like to stay in the study and be involved for longer. You do not have to decide this right now as we understand circumstances can change. Joining the study now does not commit someone to stay in the study long-term.

We want to get a good idea of a broad range of things that can impact your health and your baby's health and development, so we will ask questions about what you eat and drink, what drugs and

medications you may take, and your mental and physical health. The questionnaires can be done online or we can give you a paper copy if you prefer.

There is also a lot we can learn from your biology, so we will ask to collect biological samples such as blood, saliva, urine, and stool samples (see the list below for each sample and a short description of why we would like to collect it). If you do not want to provide a sample for any reason you can still be part of the study.

We would like you to attend an appointment at the Hunter Medical Research Institute (HMRI) during the 20th week of your partner's pregnancy. This is the building behind the John Hunter Hospital. At this appointment we would like to measure your blood pressure, height, weight and heart rate, and take some biological samples.

We are also planning to do three ultrasounds on your partner at 20, 28 and 36 weeks during your partner's pregnancy to measure the growth and development of your baby. One of these is routinely performed as part of clinical care and we will create a report for your partner's treating doctor and/or midwife. The other two are for research, however any information from these appointments which is clinically relevant to your partner's care will be given to your partner's treating doctor and/or midwife.

We will provide free parking for the appointments where we will perform the scans and collect the samples.

Study Timeline

Time Point	Duration	What will happen	Where	Who is involved
EOI (11-12 weeks)	10mins	A research midwife will discuss the study with you and explain the different aspects of the study. You will be given the opportunity to discuss the study with others before consenting.	John Hunter Hospital	You and Your partner
14 weeks	60mins	Short visit for informed consent, questionnaires, measures and biological sample collection	HMRI	Your partner
20 weeks	90mins	Ultrasound, questionnaires, measures and biological sample collection	HMRI	You and Your partner
28 weeks	90mins	Ultrasound, questionnaires, measures and biological sample collection	HMRI	Your partner
36 weeks	90mins	Ultrasound, questionnaires, measures and biological sample collection	HMRI	Your partner
Birth/on ward	30mins	Chart review, questionnaires, baby measures and biological sample collection	John Hunter Hospital	Your partner and Baby

6 weeks postpartum	30-60 mins	Questionnaires, measures and biological sample collection	HMRI	Your partner and Baby
6 months postpartum	30-60 mins	Questionnaires, measures biological sample collection	HMRI	Your partner and Baby

Clinical Measurement and Biological Samples from You

Weight and body composition

At the 20 week appointment we would like to measure your heart rate, blood pressure, weight, waist circumference and body composition at HMRI, which is where your partner will be getting their 20 week ultrasound scan.

Blood samples

We ask your permission to collect a blood sample (about 4-6 teaspoons or 20-30mL) at the same visit. Blood will be used for several different analyses; we will separate red blood cells, plasma and cells from your immune system to measure circulating markers and immune function, and will also ask permission to extract and analyse genetic materials (this is covered in a separate consent form).

Cheek swab and saliva sample

We will take a swab from your mouth to collect DNA and the natural bacteria from your mouth enzymes (called the microbiome). Your DNA can tell us information about your immune system and how this is related to allergies and disease. The microbiome can be used to study the links between oral microbiome and health outcomes.

Skin swab

We will take a swab from your skin to analyse the natural bacteria (microbiome) that live on your skin. This will be taken from your chest area.

Hair sample

We will use a sample of your hair to screen for minerals, environmental toxins and cortisol (a hormone that is associated with stress).

Toenail sample

We will ask for a clipping from your toenails to use as a toxicology screen. You can do this at home and bring them into the appointment with you.

Urine sample

We will get a sample of your urine to look at the natural bacteria that live in the urinary tract, measure kidney function and nutrient markers, and screen for toxicology.

Stool sample

A sample of your stool (poo) will be requested at 20 and 36 weeks during your pregnancy. We use an easy swab collection method which you can do at home. These samples will be used to analyse the natural bacteria (gut microbiome) and track how it changes throughout your pregnancy.

We will ask you partner to provide the samples listed above, as well as a collecting information from questionnaires, doing ultrasound scans and some additional samples such as a vaginal swab and a sample of breastmilk after your baby is born. Please discuss these with your partner and ensure you are both comfortable with the samples we are requesting. If you do not want a particular sample taken you are under no pressure to do that sample.

<u>Clinical Measurement and Biological Samples from Your Baby</u>

Baby measurements

Once your baby is born they have their weight and length measured, and a test in a Peapod machine which uses air to calculate their body composition (the amount of fat and muscle). We will request access to the birth records to obtain information on these and other measures routinely taken after birth (e.g. Apgar scores).

Cord blood sample

After birth, once the umbilical cord is cut and no longer attached some of the remaining blood that is in the umbilical cord will be collected in a tube. At the time of collection the cord is no longer connected to the baby so there is no risk to your newborn from taking a cord blood sample.

Placental sample

We will take several small tissue samples from the placenta to look at the blood vessels, structure and growth. This will happen after the umbilical cord has been cut and will not hurt your partner or baby.

Biological samples

After your baby is born we will request a urine and stool (poo) sample, a cheek swab and a skin swab from your baby. We would also like to collect these same samples at six weeks after birth, as well as a toenail and hair sample if possible.

Ultrasound for aortic intima media thickness

At six weeks we would like to see your baby and do a short ultrasound to look at your baby's heart. We will check the aorta, the largest blood vessel in the human body which carries blood away from the heart to the rest of the body. This will be done at HMRI

Lung Function

At six weeks we would like to look at you baby's lung health. We do this while they are asleep and wearing a special mask which helps to measure their breathing. The lung function test will be done by Paediatric researchers who specialise in infant and child respiratory health.

5. 'What if I don't want to take part in this study, or if I want to withdraw later?'
Participation in this study is completely voluntary. It is up to you whether or not you participate. If you decide not to participate, it will not affect your relationship with the staff caring for your partner or your baby.

If you decide to withdraw from the study, you have the option of withdrawing all information relating to you and have any biological samples that have been taken destroyed. An exception to this is in the case of an adverse event, or a serious adverse event, where the information needs to be retained for regulatory reporting.

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

6. How Many Visits?
We will book four visits throughout your partner's pregnancy at HMRI to do ultrasounds, collect biological samples, do some measurements and collect questionnaires. We are requesting you come with your partner to the 20 week appointment. This is the most common appointment that partners attend during pregnancy, as you can get a good look at your baby on the screen, which is why we have chosen this time to ask for you to come in.

7. 'How is this study being paid for?'
The study is supported through philanthropy and the Mothers and Babies Research Centre at Hunter Medical Research Centre.

8. 'Are there risks to me in taking part in this study?'
The side effects of having blood collected may include bleeding or bruising at the injection site and possible dizziness and/or possible fainting. We have trained, experienced staff to take the samples to minimise any discomfort. Please advise the research team if you normally feel dizzy or faint when you have blood collected.

After birth the umbilical cord is cut and the placenta is delivered. Remaining blood that is in the umbilical cord will be collected in a tube. Therefore, there is no risk to mother or baby when we take blood from the umbilical cord.

9. 'Will the study cost me anything??'
As participation is voluntary you will not be paid for the study, however we will provide parking for all of your research related visits.

10. 'Will I benefit from the study?'
You, your partner and your baby are not likely to benefit directly from this study, however the results may have a positive impact on the way we research and deliver pregnancy and child health care. The on-on-one midwifery contact and regular ultrasounds which allow you to see how your baby is growing might be something you enjoy as part of the study.

11. 'How will my privacy be protected?'

Only the researchers on the study will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. The study results may be presented at a medical conference or in a scientific publication, but individual participants will not be identifiable in such presentations.

Your personal information will be accessed, used and stored in accordance with Commonwealth Privacy Laws and the NSW Health Records and Information Privacy Act 2002. All information will be stored on a password protected HMRI Database (REDCap) which is both physically and virtually secure.

If you decide to withdraw from the study, you can request any data collected be withdrawn and destroyed. In some cases, your information may already be included in data analysis that has already been published in scientific publications or presented at a conference. In these cases, it may not be possible to withdraw your individual information from these presented data. Please be assured, any information used for publication or presentation will not be traceable back to your identity.

12. 'What happens with the biological samples?'

At all times your privacy will be maintained; your biological samples will be stored in a secure laboratory with an anonymous code before they can be analysed. We will store the codes and names in a secure locked file that can only be accessed by the research team.

With your permission, we will use blood samples from you and your baby to perform genomic testing. Genomic testing involves studying genes and their links to health and disease. The type of genomic testing we will perform on your blood samples will not provide any information about your health, or risk of disease for you, your baby or your family. On the extremely rare occasion that information is obtained about the health of you, your baby or family is found, we will inform your nominated General Practice Doctor, who will discuss these results with you. A separate consent form covers this type of analysis.

Samples collected from this study may be stored and used for future studies in pregnancy by researchers in our department and/or national/international collaborators. Any future proposed research study in which your blood sample is used will be reviewed by the Hunter New England Research Ethics Committee and The University of Newcastle Human Ethics Committee prior to commencement.

Although the biological samples will be stored in a biobank facility they will remain your property, as such if you have a clinical reason to access them, or the data and test results from any of the analyses we have performed you can request this through the Study Manager. If you wish to withdraw any or all of your samples at any time you can contact the study manager or one of the Research Midwives via phone (02 4042 0345) or email (new1000@newcastle.edu.au).

13. 'What happens with the results?'

We plan to publish the results of the study in peer reviewed journals. Results of the study will be presented to researchers and clinicians via presentations at national and international conferences, and publication in peer reviewed journal articles. Your privacy will be protected as the information will be de-identified (for more information on protecting your privacy see section 11).

14. 'What should I do if I want to discuss this study further before I decide?'

When you have read this information, one of the researchers will discuss it and any queries you may have with you. If you would like to know more at any stage, please do not hesitate to contact Professor Craig Pennell on the number listed below. If you want to discuss the study with family members or your baby's other parent, you are welcome to take the time to do so before you decide whether to participate in the study.

Professor Craig Pennell
Chair Obstetrics and Gynaecology
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13. 'Who should I contact if I have concerns about the conduct of this study?'

This study has been approved by the Hunter New England Human Research Ethics Committee. If you have concerns or complaints about the conduct of this study you should contact:

Dr. Nicole Gerrand PhD
Ethics Manager
Research Office
Hunter New England Local Health District
Level 3 POD, HMRI, Lot 1 Kookaburra Circuit NEW LAMBTON HEIGHTS, NSW. 2305
Tel: (02) 4921 4950
Email: Nicole.Gerrand@health.nsw.gov.au

The Manager is the person nominated to receive complaints from research participants. You will need to quote reference number 2020/ETH02219.

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

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PARTICIPANT CONSENT FORM PATERNAL

I, ... (participant name),

of ……..... (participant's address),

have read and understand that the study will be conducted as described in the Information Statement, a copy of which I have retained.

I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or potential side effect and of their implications as far as they are currently known by the researchers.

I agree to participate in this study and understand that I can withdraw at any time without providing a reason.

I understand that my personal information will remain confidential to the researchers.

I have had the opportunity to have questions answered to my satisfaction.

I hereby agree to participate in this research study.

Name of participant: .....

Signature of participant: .....

Date: .....

Declaration by person conducting the consent process

I, the undersigned, have fully explained this research to the participant named above.

Name: .....

Signature: .....

Date: .....