

The **PROMISE** Study

(Predicting intrapartum fetal compromise at term using the fetal cerebro-placental ratio and placental growth factor)

Participant Information Sheet

Research Team:	Prof Sailesh Kumar (Principal Investigator)	Project Sponsor:	Mater Health Services	
	Prof Vicki Clifton (Associate Investigator)		Project Funding:	Mater Foundation
	Dr Helen Sherrell (Associate Investigator)		Location:	Mater Mothers' Hospital

Thank you for taking the time to read this information sheet and considering participation in this study.

1. Introduction

Worldwide, complications in labour are a major contributor to poor pregnancy outcomes including stillbirth and poor condition of babies after birth. In Australia, lack of oxygen to a baby after the onset of labour (i.e. fetal distress) in an otherwise healthy pregnancy is one of the top three causes of death in singleton pregnancies after 37 weeks. Our previous research has shown that a late pregnancy ultrasound scan combined with a blood test from the mother measuring the levels of a placental hormone can potentially identify pregnancies at risk of fetal distress. We would now like to assess the value of this screening test in a pilot study at the Mater Mothers' Hospital.

You are therefore being invited to participate in a research study investigating whether introduction of this test at 37 weeks gestation reduces the number of women who develop this complication (fetal distress) and their need for an emergency caesarean section. The purpose of this information sheet is to clearly explain the study and help you decide if you would like to participate. Please take your time to read this information before consenting to participate. You may also like to discuss this study with family, friends or your midwife and obstetrician. Participation in this research is voluntary. If you don't wish to take part you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the study, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2. What is the purpose of the study?

The purpose of this study is to determine whether the introduction of a pre-labour screening test at 37 weeks results in less babies having fetal distress in labour. Fetal distress can occur when a baby does not receive enough oxygen in labour. This is why some babies need emergency delivery by caesarean section, forceps or vacuum.

The screening test will involve taking a blood test from you to measure a pregnancy related hormone (placental growth factor (PIGF)) and performing an ultrasound scan to look at blood flow in your baby. Specifically, we will measure the ratio of resistance of blood flow in the brain and umbilical cord - called the Cerebro-Placental Ratio or CPR. Our previous work suggests that low levels of PIGF (less than the 33rd centile) **and** a low CPR (less than the 20th centile) are more common in pregnancies that develop fetal distress and require emergency caesarean section for delivery.

Document Title:	Predicting intrapartum fetal compromise at term (PROMISE Study) PICF				
Version No:	7.1	Date:	27 th April 2018	Page:	1 of 5

3. Why am I being asked to take part?

You are eligible to take part in this study if you have single baby with cephalic presentation (i.e. head first) and planning a vaginal delivery. You have **NOT** been asked to participate because we are concerned that you are at greater risk of fetal distress. We are inviting all eligible women to participate.

4. What will happen to me if I take part?

If you decide to take part in this study:

- a) You will need to read and sign the consent form.
- b) You will then be randomised into either the ‘**screening test**’ group or ‘**no screening test**’ group. This is because randomisation (like the toss of a coin) guarantees that people are selected to receive the screening test by chance, so that both groups are similar except for whether they had the screening test or not.
- c) If you are randomised to the ‘**no screening test**’ group you will receive normal obstetric care and your pregnancy will progress as usual. We will however collect your birth outcomes after delivery so that we can ascertain if there are any differences in outcomes between both groups.
- d) If you are randomised to the ‘**screening test**’ group you will have an ultrasound scan between 37-38 weeks gestation to measure your baby’s size and the CPR. This scan will take about 30-45 minutes and will be arranged to coincide with an antenatal appointment or at another convenient time for you. Before your scheduled ultrasound you will have a blood test to measure your level of PIGF. This blood test will be collected by our study Doctor or Midwife at your scan or can be done up to 2 days earlier at any Mater Pathology department that is convenient for you.
- e) If your screening test is ‘**negative**’ (your CPR and/or PIGF level is not low) - you will receive normal obstetric care for the rest of your pregnancy, labour and delivery.
- f) If your screening test is ‘**positive**’ (**both** your CPR and PIGF level are low) – an Obstetric Doctor from our study team will discuss your result. As the purpose of this test is to identify babies at risk of fetal distress, we will recommend starting your labour (induction of labour) within the next 7 days. If you decide not to be induced, we will recommend weekly monitoring of your baby until you go into labour and your baby is delivered.
 - It is important to note that the Obstetricians and Midwives caring for you in labour will not know the exact details of your CPR or PIGF level - they will only know that your screening test result was either “screen positive” or “screen negative”.
 - If however, something unexpected is found on your ultrasound scan (e.g. if your baby is in an unusual position, or if your baby is very small or very big or the blood flow in the umbilical artery is abnormal) this information will be shared with the Obstetricians and Midwives caring for you as this may impact on your care.
 - If your screening test is ‘positive’ and you go into labour prior to your planned induction, you will receive normal obstetric care with the addition of recommending continuous fetal heart rate (CTG) monitoring.
- g) After birth, all women in this study will have a small sample of umbilical cord blood collected for analysis of acid and oxygen levels. From some additional participants in the study we would also like to collect samples of your placenta and some extra umbilical cord blood after the delivery of your baby. None of these additional samples will impact on your care in labour or after delivery. Specifically, it will not impact on your choice of having delayed cord clamping or a natural third stage of labour. However, if some extra umbilical cord blood is collected for the study it will impact on your ability to donate your baby’s cord blood to the Queensland Cord Blood Bank at The Mater. If you are happy for us to collect these additional samples, there is a check box option on the consent form.

Women who screen positive will receive exactly the same care during their labour as those not participating in the study or those who screen negative. If you require emergency medical assistance at any time, this will still happen.

Document Title:	Predicting intrapartum fetal compromise at term (PROMISE Study) PICF				
Version No:	7.1	Date:	27 th April 2018	Page:	2 of 5

5. What happens if I choose not to participate in the study?

Participation in the study is completely voluntary. If you do not wish to participate, you do not have to. If you decide to take part and later change your mind, you are free to withdraw at any stage. Your decision not to participate (including withdrawal) will not affect the care you receive. If you wish for stored samples to be destroyed and not used for future research you can contact the Study Team (by phone, email or letter) and ask for your samples to be withdrawn from the study. Any remaining sample will then be removed from storage and destroyed following the protocols of Mater Pathology.

6. What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from taking part in this research and we will not know if introducing this screening test does result in an improvement in outcomes until the study is completed. However, if our hypothesis is proven correct, this test may benefit future pregnant women and will help guide how we care for women in pregnancy and labour. As late pregnancy ultrasounds are not currently routine for most women, participants in screening test arm of this study will have the benefit of visualizing their baby and having an assessment of its wellbeing.

7. What are the possible disadvantages and risks of taking part?

Women who screen positive and are recommended to have induction of labour may have anxiety about their pregnancy outcome. However, there is now very good evidence showing that women who have an indication for induction at term have reduced rates of emergency caesarean section and better perinatal outcomes compared to expectant management.

Some women may find the process of induction (either inserting a gel in the vagina or a balloon catheter in the cervix) uncomfortable. However, induction of labour is a very common obstetric procedure performed for many different reasons and most women do not experience complications. You will not incur any costs as a result of participation in the study.

Some women randomised into the ‘no screening test’ may feel disappointed or anxious about not receiving the opportunity to have an ultrasound scan. However, it is not yet known if a third trimester ultrasound screening test confers any advantage to women and regardless of which group they are allocated to all women will receive careful monitoring during their pregnancy in line with best practice and current hospital policies and guidelines.

8. What will happen to my blood tests and specimens?

The blood tests in this study are for research purposes only. The exact results of your maternal PIGF blood test will not be released to your Doctors or Midwives and will therefore not directly influence your care. If you consent to a sample of your cord blood and placenta being collected for research, the results of these will again not be released to your obstetric team. They will be tested in a laboratory to look for features that may relate to fetal distress. These samples will be securely stored in a Mater Research Institute or Mater Pathology laboratory freezer for up to 10 years and may have extended use in further studies at Mater also directly related to fetal distress or intrapartum hypoxia. Any additional future studies will undergo the same review process by a Human Research Ethics Committee as this study has.

9. What will be done to ensure information about me remains private and confidential?

By signing the consent form you are telling us that the research team can use your personal and health information and access your medical records for the **sole purpose** of this research project. Once collected, any identifying information will be removed and replaced by a study number. The collected specimens and results from any collected specimens will also be linked to your unique study number. The information will then be stored on a hospital computer and be password protected. Research documentation will be stored for at least 33 years (baby data) and for 15 years (maternal data) respectively.

Document Title:	<i>Predicting intrapartum fetal compromise at term (PROMISE Study) PICF</i>				
Version No:	7.1	Date:	27 th April 2018	Page:	3 of 5

10. What will happen to the results of the research study?

Parts of this project will be used for Dr Helen Sherrell’s research higher degree (PhD) through the University of Queensland. It is anticipated that the study will run for three years. The results will also be presented at national and international meetings and be published in medical and scientific journals. However, no participant identification will ever be used and all results will be anonymized.

11. Who may I contact for further information or if I have concerns?

In the event of any serious adverse event occurring as a result of your participation in this study, you will be cared for in accordance with the Mater Mothers’ Hospital’s clinical protocols to ensure your medical wellbeing. The sponsor, Mater Health Services holds insurance policies which apply to this study. This does not affect your legal right to seek compensation.

You are of course free to discuss your participation in this study or ask any questions by contacting the research team:

Professor Sailesh Kumar Mater Research Institute/University of Queensland
 Aubigny Place, Raymond Terrace, South Brisbane, QLD 4101
 Phone: +617 3163 8844
 Email: sailesh.kumar@mater.uq.edu.au

Dr Helen Sherrell Mater Research Institute/University of Queensland
 Aubigny Place, Raymond Terrace, South Brisbane, QLD 4101
 Phone: 0439782607
 Email: promise@mater.org.au

This study has been reviewed and approved by the Mater Health Services Human Research Ethics Committee (EC00332). Should you wish to discuss the study in relation to your rights as a participant, or should you wish to make an independent complaint, you may contact the Coordinator or Chairperson, Human Research Ethics Committee, Mater Health Services Level 2 Aubigny Place, Raymond Terrace South Brisbane 4101 or telephone (07) 3163 1585, email: research.ethics@mmri.mater.org.au

Document Title:	<i>Predicting intrapartum fetal compromise at term (PROMISE Study) PICF</i>				
Version No:	7.1	Date:	27 th April 2018	Page:	4 of 5

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Participant Consent Form

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		Project Funding:	Mater Foundation
		Location:	Mater Mothers' Hospital

Declaration by Participant

- I have read the Participant Information Sheet or someone has read it to me in a language I understand.
- I understand the purposes, procedures and risks of the research described in the project.
- I have had the opportunity to ask questions and I am satisfied with the answers I have received.
- I give permission for my Doctors and members of the research team to access any relevant personal and health information retained by Mater Health Services for the purposes of this project. I understand that such information will remain confidential.
- I consent to the storage and use of blood samples taken for me, as described in the relevant section of the Participant Information Sheet, for this specific research project.
- I agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I consent to the collection, storage and analysis of additional cord blood and placenta samples following the delivery of my baby.

I consent to these samples being stored for up to 10 years in a Mater Pathology Lab freezer and used in further studies also directly related to fetal distress or intrapartum hypoxia at Mater Misericordiae Limited.

Name of participant _____

Signature _____ Date _____

Declaration by Investigator

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

Name of investigator _____

Signature _____ Date _____

I would like to receive a summary of the study findings at the completion of the project.

(NB: please provide a copy of the signed statement to the participant if requested)

Document Title:	Predicting intrapartum fetal compromise at term (PROMISE Study) PICF		
Version No:	7.1	Date:	27 th April 2018
		Page:	5 of 5