TO UNDERSTAND BIRTH (TUB) STUDY

WOULD YOU LIKE TO PARTICIPATE IN A STUDY LOOKING AT PREDICTING AND PREVENTING PRETERM BIRTH AND OTHER PREGNANCY COMPLICATIONS?

Chief Investigators:
Professor Roger Smith, Mothers and Babies Research Centre, HMRI
Professor Craig Pennell, Maternity and Gynaecology Department John Hunter Hospital
Associate Professor Kirsty Pringle, Mothers and Babies Research Centre, HMRI Phone 40420372
Dr Jonathan Paul, Mothers and Babies Research Centre, HMRI

What is the purpose of the study?
Our research team is studying how pregnancy and labour works to find ways of preventing pregnancy complications such as preterm birth, fetal growth restriction, preeclampsia and stillbirth. To understand the process of pregnancy and labour, we need to study hormones and other biological factors at play in the mother, the uterus, the placenta, umbilical cord blood and the membranes that surround the baby. By better understanding how these processes work, we can then develop new treatments.

What does the study involve? You may be asked to consent to one, some or all of the following:

1. **Blood sample collections**: A blood sample from a vein of approximately 5-15ml of blood. Where possible, we will perform this at the same time as any routine blood test that you have as part of your clinical care throughout your pregnancy. We may also ask you to give serial blood samples (maximum 3 times) throughout your pregnancy.

2. **Placenta sample collection:** The donation of your placenta and its surrounding membranes after your baby is born and collection of cord blood from the placenta.

3. **Uterus tissue sample collection:** The decision to have a caesarean is made by your medical team and yourself independently of this research project. If you have a caesarean section we will ask your consent to remove a very small piece of uterus from where your uterus has been cut for your caesarean operation (a matchstick size), and a sample of amniotic fluid surrounding the baby.

NB: If you consent to be involved in this study **it does not mean you are going to have a caesarean** and **signing up for the study will not increase the chances of you having a caesarean**. If you do have a caesarean, and if you agree, your obstetrician will remove a small piece of your uterus (about the size of half a matchstick).

Storage of samples for future studies of pregnancy and associated complications
Some of the samples collected from this study will be stored and used in the future for further studies of pregnancy and labour. Students may also use these samples now and in the future as part of their research projects *related to pregnancy and labour*. All the samples collected will have no information that could identify you so that your privacy is maintained. We may also collect other relevant information about you and store it in a computer so that we can link your tissue samples and your clinical details. We will obtain this information from your medical record and we will securely store your information in the Mothers and Babies Research Centre at the Hunter Medical Research Institute, in accordance with the Hunter New England Local Health District requirements to ensure privacy and confidentiality. Any research study in which your tissue will

be used will be reviewed, and if the research adheres to the requirements of the National Statement of Ethical Conduct in Research Involving Humans (2007) will be approved by the Hunter New England Human Research Ethics Committee and The University of Newcastle Human Ethics Committee before it commences.

If you have any questions about the study, you can contact us by telephone at the above numbers. If you agree to be part of the study, you can sign the consent form and return it to the research midwife today or if you would prefer, take this information sheet home and discuss with your partner. You can return the information sheet and consent form prior to your delivery and give it to the midwife.

What do I need to tell the doctor before I participate?

We would like to know if you have any illnesses such as asthma, diabetes or hypertension. We would also like to know if you smoke cigarettes and how many you smoke each day. Please tell us if you take any other medicines including herbal medicines or medicines bought from the supermarket, chemist or health food shop.

Is the information collected confidential?

We will need to obtain some information about your pregnancy from your medical records, including the length of your pregnancy, your age, the reason for your caesarean (if relevant to your delivery), how many other pregnancies you have had, and if you are having a caesarean whether your labour had started at the time of your caesarean. Only our chief investigators or research midwives will access your medical records. We will keep any information we collect about your pregnancy confidential.

What if I change my mind?

Taking part in this study is completely voluntary and if you participate you are free to withdraw from the study at any time without giving a reason. Decisions you make regarding participation will not affect your access to care and services you would normally receive. If you choose to withdraw from the study just let the doctor or midwife know.

What if I have a complaint about this study?

This research has been reviewed and approved by the Hunter New England Human Research Ethics Committee and the University of Newcastle Human Research Ethics Committee.

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to :

Dr Nicole Gerrand
Manager, Research Ethics and Governance Office
Hunter New England Human Research Ethics Committee
Hunter New England Local Health District
Locked Bag 1
New Lambton NSW 2305

Telephone: 4921 4950

Email: HNELHD-HREC@health.nsw.gov.au

Professor Roger Smith
(Director Mothers and Babies Research Centre, on behalf of the staff of the Mothers and Babies Research Centre)

CONSENT TO PARTICIPATE IN RESEARCH
TO UNDERSTAND BIRTH (TUB) STUDY

Chief Investigator to contact: A/Prof Kirsty Pringle 40420372

This study is looking at how pregnancy and labour works. We want to understand this process so we can find ways of preventing preterm birth and other pregnancy complications.

It is essential that you read and understand the information sheet, which gives details of what will happen during the study. Please ask the doctor or nurse to answer any questions you have before signing the consent form. You may telephone the research team anytime.

All information gained from this study will remain confidential and personal identifying information will be deleted from all records when the study is complete.

CONSENT

I, (print name) _____,

of (print address) _____

have been asked to participate in the above research project and give my free consent by signing this form. I understand that:

1. The research project will be carried out as described in the Information Sheet, a copy of which I have retained.

2. By signing this consent form I am not signing up for a caesarean operation. If I do not volunteer, or decide to withdraw, my decision will be accepted and my non participation will not affect the treatment I am receiving.

3. If I have a caesarean section, by signing these consent forms I have agreed to provide a sample of uterine tissue and amniotic fluid at the time of my caesarean operation.

4. My consent to participate is voluntary and I may withdraw from the trial at any time. I do not have to give a reason for the withdrawal of my consent.

5. I acknowledge that I have read the information statement, which explains why I have been selected, the purpose for storing the tissue and the associated issues relating to privacy and confidentiality, and the statement has been explained to me to my satisfaction.

6. I consent to the research team storing my tissue and blood samples future research as described in the attached information statement.

7. Before signing this consent form, I have been given the opportunity of asking any questions about the implications of my tissue being stored for future research and I have received satisfactory answers.

8. I understand that I can request that my stored tissue be destroyed at any time without affecting my relationship to the Hunter New England Local Health District or any of the personnel involved.

9. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

If I wish to raise matters of concern or complaints, I can contact
Dr Nicole Gerrand
Manager, Research Ethics and Governance Office
Hunter New England Human Research Ethics Committee
Hunter New England Local Health District
Locked Bag 1
New Lambton NSW 2305

Telephone: 4921 4950

Email: HNELHD-HREC@health.nsw.gov.au

_____ _____

Please PRINT your name **Please sign here**

_____

Date

_____ _____

Person obtaining consent **Consenter's signature**

_____

Date

Signature of Chief Investigator
(Professor Roger Smith)