### **Later contact:**

We would also like to send you a questionnaire at 6 weeks, 6 months and 1 year after the birth of your baby, to see how you and your baby are. We will ask questions about any pain you might have, satisfaction with birth, breast feeding, depression since delivery, sexual function, incontinence and your baby's general well-being. This information will remain confidential and will only be identified with a study number. This will be sent from the coordinating centre at Royal Prince Alfred Hospital, Sydney. The questionnaire can be sent either by email or standard post depending on your preference. All aspects of the study, including results will be strictly confidential and only the researchers will have access to it.

#### Risks

The risks from this procedure is very rare. There has only been one case reported (world wide) of cord prolapse following this procedure. This means that the umbilical cord comes out of the vagina in front of the baby's head. This situation requires an emergency delivery, usually by Caesarean section.

#### **Benefits**

While we intend that this research study furthers medical knowledge and may improve delivery of babies in the future, it may not be of direct benefit to you. However your delivery might possibly be less complicated by being in the study.

## **Voluntary participation**

Participation in this study is entirely voluntary. You do not have to take part in it. If you do take part, you can withdraw at any time without having to give a reason. Whatever your decision, please be assured that it will not affect your medical treatment or your relationship with the staff who are caring For you.

We suggest that if you are considering volunteering for this study you discuss the study with the person/people who will be supporting you during your labour.

#### **Further Information**

When you have read this information, if you have any further questions, one of the researchers can be contacted to discuss it further with you. If you would like to know more at any stage, please feel free to contact If you would like to know more at any stage, please feel free to contact Dr Felicity Park or Dr Wendy Carseldine on JHH Switch 049213000.

## Confidentiality

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



This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District. Any person with concerns or complains about the conduct of this study should contact the Executive Officer on 02 9515 6766 and quote protocol number X11-0410.

The conduct of this study at the Royal Alfred Hospital has been authorised by the Ethics Review Committee (RPAH zone) of the Sydney Local Health District. Any person with concerns or complains about the conduct of this study may also contact the Research Governance Officer on 02 9515 6766 and quote 12/HNE/637



Persistent Occipito-Posterior

OUTcomes following manual rotation

www.popout.me

Information Sheet
for women in labour whose
baby is in the posterior
Position (Looking upwards)

# Thank you for taking the time to read this information leaflet

You are invited to take part in a research study to try to improve the outcome for both mothers and babies when the baby is lying in the occiput posterior (OP) position (looking upwards) or the occiput transverse (OT) position (looking sideways) in the late stages of labour.

The study is being conducted within RPA Hospital, by: Dr Felicity Park and Dr Wendy Carseldine.

The study is part of a national collaborative study coordinated by the Royal Prince Alfred Hospital, RPA Women and Babies, Sydney and supported by a grant from the National Health Medical Research Council (NHMRC).

## **Background**

Most babies are in an occiput anterior (OA) position (baby is looking downwards) before and during delivery. When the baby is in the OP or the OT position, problems can occur as the baby's head presents a wider profile in those positions.

OP position can cause problems such as longer labour, more painful labour, increased need for epidural anaesthetic, increased rate of tears of the vagina, sometimes into the anus and rectum, increased bleeding after the birth and increased risk of infection in the uterus after delivery.

When the baby is in the OP or OT position and the mother's cervix is fully dilated, labour. It is often necessary for the woman to have a forceps, vacuum or caesarean birth, particularly if the baby has not been born after one hour of pushing.

Another option is manual rotation, a procedure to turn the baby's head to the OA position at the beginning of the second stage of labour. There is some evidence that this procedure may reduce the risk of instrumental or caesarean delivery. This procedure is currently practised worldwide by some midwives and obstetricians. The objective of this study is to determine the effectiveness of elective manual rotation in the management of OP and OT position early in the second stage of labour.

We recently completed a small study of 30 pregnant women to test if this study is achievable and whether women were happy to be part in such a study. We were reassured that our study was well accepted by the women who participated as well as by their midwives and doctors.

## What will happen?

If you agree to participate in this study, you will be asked to sign the participant Consent Form. When you are in labour and are fully dilated, a bedside ultrasound will be performed to determine the position of your baby. If your baby is in the OP or OT position, then you will be allocated at random (like the toss of a coin) by a computer, to either having the procedure to turn the baby's head to the OA position or not. The study obstetrician would then be called to labour ward. On arrival he or she would repeat the abdominal ultrasound to ensure your baby is still in either the OP or OT position. Once that is confirmed he or she would perform an internal examination.

If you are in the group allocated to have an attempt at turning the baby's head, the obstetrician would, with each contraction, apply gentle pressure with the aim of slowly turning the baby's head so that it faces downwards. The procedure is perceived to be no more uncomfortable than a routine internal examination. But levels of discomfort may vary and some women may experience more discomfort. In such circumstances, if a woman does not have an epidural, nitrous oxide or Fentanyl can be offered. The procedure takes 4-5 contractions to perform (about 6-10 minutes). If you are in the group allocated to have a vaginal examination alone, the obstetrician would feel the position of the baby's head, but would not attempt to turn it. If you choose not to participate you will receive standard care.

Both groups will then be allowed to labour as usual, and any further management would be decided by you and your team to ensure the best outcome for both you and your baby. Neither you nor the midwives and doctors looking after you will know the group to which you have been allocated. This is necessary because we know that knowledge of the treatment groups can bias the results of the study.

The person who would do the vaginal examination would be one of the hospital's obstetric doctors with experience in performing this procedure, but would not necessarily be anyone who has previously cared for you during your pregnancy. Regardless of which group you are in, your own team will continue to take care of you after the study procedure according to your and your baby's needs.