Royal North Shore Hospital

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

CLINICAL TRIAL

APProve: C**A**n **P**robiotics Im**Prove** Breastfeeding Outcomes?

Invitation

You are invited to participate in a clinical trial called APProve. This trial is being conducted by Professor Jonathan Morris, Ms Diana Bond and Dr Natasha Nassar from the Kolling Institute, Department of Obstetrics and Gynaecology, University of Sydney, based at the Royal North Shore Hospital, St Leonard's.

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?'

The purpose of this study is to investigate whether taking oral probiotics can improve breastfeeding outcomes during the first two months after delivery. Research has shown that probiotics are effective for treating certain infections in mothers and infants, but their role in preventing disease and improving health in relation to breastfeeding has not yet been explored.

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

You are eligible to participate in this study because you have indicated that you intend to breastfeed your baby after you deliver.

3. 'What if I don't want to take part in this study or if I want to withdraw later?'

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you. New information about the treatment being studied may become available during the course of the study. You will be kept informed of any significant new findings that may affect your willingness to continue in the study. 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.

4. 'What does this study involve?'

If you agree to participate in this study, you will be asked to sign the Participant Consent Form and answer a few questions about your pregnancy and any past pregnancies, age, education, ethnicity and marital status, smoking and alcohol use, medical conditions, and recent use of antibiotics. We will then register you into our mobile phone application system. From this time, you will be asked to complete a short questionnaire via a web-link delivered by SMS each week until your baby is 2 months old. The questionnaire will collect information about you and your baby's general well-being, unscheduled doctor's visits, and medication intake and take less than 5 minutes to complete. Once your baby is born, an additional daily questionnaire will ask about pain, infection and infant feeding and will take less than 15 seconds to complete. Additional information about your birth and your baby will be collected from your hospital medical record. This will include gestation at delivery, method of birth, antibiotics at delivery, complications of birth, length of hospital stay, infant sex, birthweight, Apgar score and initiation of infant feeding.

This study will be conducted over a period of one year. After your baby is born, you will be randomised to either the "probiotic" group or the "placebo" group. A blood sample may also be collected from you at the time of randomisation. Whichever treatment you receive, you will be asked to take the treatment daily for 2 months by dissolving the contents of the provided sachet into a cold drink and drinking it immediately. It is important that you keep the boxes of sachets refrigerated to maintain their stability. It is recommended the treatment be taken at the same time each day and you complete the daily questionnaire once you have received the SMS text at 10am. APProve will send you a brief SMS reminder if you forget to take the treatment by 8pm.

You are encouraged to see your doctor if you have any health concerns. If you are unwell and need to take any medications, including antibiotics, continue to take the study treatment at least 2 hours after you take your medication. If you forget to take the treatment, do not double-dose, but continue your daily routine as soon as possible. It is important that you do not take any other probiotics during the 2 months you are on the treatment.

If we collect breast milk or faecal samples as part of this study, we will provide you with small sample pots for you to collect a small amount of your breast milk as well as a small stool (poo) sample collected from your baby's nappy when he/she is 2 months old. You will be asked to bring these samples with you in a cooler bag to a scheduled 2 month follow-up visit, done either at your home or at a designated location at RNSH. We will also ask you to return any unused treatment sachets. At this time we will conduct a health and well-being interview which should take approximately 30 minutes, and may collect a small sample of blood. We will collect the results of any samples collected from your medical records. We will also contact you at 6 months and 12 months after delivery to complete a follow-up questionnaire by email, post, or SMS web-link (whatever your preference) which should take only 20 minutes to complete.

You will be participating in a 'double-blind randomised controlled trial'. Sometimes doctors don't know the best way of treating patients with similar characteristics so comparisons need to be made between different treatments. To do this, study participants are put into groups and given different treatments, and the results are compared to see whether one treatment is better. To ensure the groups are similar to start with, a computer allocates each study participant into a group randomly, like the flip of a coin. Neither the doctor nor the study participant can decide which treatment the participant receives. "Double blind" means that neither the study team nor the study participant knows which treatment the participant is receiving (although, if the study team needs to find out, they can do so). A placebo is a dummy treatment that looks like the genuine product but contains no active ingredient. In this trial, we will be comparing the probiotic treatment to a placebo.

In addition, to minimise the number of questions and time asked of you, the researchers would like to have access to you and your baby's medical records and pathology reports. These will provide us with information about your labour, birth, hospital stay and sample results.

5. 'How is this study being paid for?'

The study is being funded by the Perinatal Research group at the Kolling Institute, the University of Sydney and conducted at the Royal North Shore Hospital. The investigators have no conflict of interests related to this study. All treatment sachets are being donated by a commercial probiotic company.

6. 'Are there risks to me in taking part in this study?'

We do not anticipate that you will suffer any unexpected risks as a result of this study. The probiotics used in this trial are approved by the Australian Register of Therapeutic Goods and are not associated with any adverse effects. Known maternal side effects may include mild gas or bloating. There are no known side effects to breastfeeding infants while mothers are taking this probiotic.

7. 'What happens if I suffer injury or complications as a result of the study?'
We do not anticipate that you will suffer any injuries or complications as a result of this study. However, if you have any concerns you should contact the study coordinator, Ms Diana Bond on 9462 9796.

8. 'Will I benefit from the study?'
This study aims to further medical knowledge about ways to improve the health of mothers and babies while breastfeeding. We will not be able to directly attribute any positive benefits to the treatment until after the trial.

9. 'Will taking part in this study cost me anything, and will I be paid?
All treatment sachets required as part of the research project and sample pots for the collection of samples will be provided to you free of charge. You will be given a complimentary parking voucher for your 2 month follow-up visit if conducted at the RNSH. Please note that the daily data collection on your mobile phone browser may require minimal data usage.

10. 'What will happen to my samples after they have been tested?'
Any blood, milk or stool samples you provide will be disposed of at the completion of the study.

11. 'How will my confidentiality be protected?'
Any identifiable information that is collected about you in connection with this trial will remain confidential and will be disclosed only with your permission, or except as required by law. All health information and samples will be identified using a unique number and kept separate from your personal details. The information downloaded from the mobile phone application system will be identifiable only by the study number and re-identified with your contact details only for the purpose of sending out the follow-up questionnaires. All identifiable printed records will be kept by the trial coordinator in a locked filing cabinet in the RNSH campus and electronic research records held on a secure server at the University of Sydney on a password−protected computer with access limited to the research staff.

12. 'What happens with the results?'
If you give us your permission by signing the consent document, results of this trial may be published in a study report or medical journal and presented at conferences or other community or professional forums. Results will also be provided to the Human Research Ethics Committee for monitoring purposes, and to you, if you wish. In any publication, information will be provided in such a way that you cannot be identified.

13. 'What happens to my treatment when the study is finished?'
As this treatment is not currently part of routine care, this will not have any impact on normal care following the birth of your baby.

14. 'What should I do if I want to discuss this study further before I decide?'
When you have read this information, a member from the study team will discuss it with you and answer any queries you may have. If you would like to know more at any stage, please do not hesitate to contact Ms Diana Bond on 9462 9796 or visit our webpage: approvetrial.org.au.

15. 'Who should I contact if I have concerns about the conduct of this study?'
This study has been approved by the Northern Sydney Local Health District HREC. The conduct of this study at the Royal North Shore Hospital has been authorised by the Research Governance Officer at Northern Sydney Local Health District. Any person with concerns or complaints about the conduct of this study may contact the Research Ethics and Governance Office on 02 9926 4590 and quote protocol number [HREC/14/HAWKE/358].

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.