Participant Information Sheet

Study title: Early versus Late **A**rtificial **R**upture Of **M**embranes during oxytocin induction of labour: A Randomised Controlled **Trial**

[lay study title] **(ARM Trial)**

Locality: Auckland District Health Board

Ethics committee ref.: *NZ/1/C5A6117*

Sponsor (if applicable): *University of Auckland*

Lead investigator: Meghan Hill, MBBS, MS

Contact phone number: (09) 923 5025 x 89493

You are invited to take part in a study entitled "Early versus late artificial rupture of membranes during oxytocin induction of labour: A randomised controlled trial". This study is assessing whether performing an artificial rupture of membranes early during an oxytocin induction is better than performing it later during the induction. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 10 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

We are asking you to consent to the Early versus Late **A**rtificial **R**upture Of **M**embranes during oxytocin induction of labour: A Randomised Controlled **Trial (ARM Trial)**. You are being approached because you are pregnant and attending the Auckland District Health Board (ADHB) for care and undergoing an induction of labour with oxytocin. The aim of this

research is to find out whether it is better to perform an Artificial Rupture of Membranes (ARM) at the start of an induction of labour, or whether it is better to wait until later in labour, when the cervix is more dilated. We will be looking at whether one approach leads to more effective or safer outcomes than the other.

This kind of study is called a Randomised Controlled Trial (RCT). The idea is that researchers take a group of women needing treatment, in this case, an induction of labour, and change part of that treatment in some of the women to see if it makes any difference to outcomes. In this case, the intervention is the timing of the ARM. This kind of research can help us to understand the best, and safest way to perform an induction of labour. It can thereby allow us to implement the best ways to induce labour for other women in the future.

When a provider performs an ARM, they do so by checking your cervix and placing a small, plastic instrument in between their fingers. This instrument has a very small hook on the end that they use to place a small hole in the amniotic membrane. Many people call this 'breaking your water'. The timing of this procedure is different in different hospitals and different countries. Some people believe that an ARM should be done at the start of the induction of labour and some believe that it is better done later. We intend to investigate whether it makes a difference to outcomes for mothers or for babies to perform the ARM early or late.

We intend to recruit about 500 women into this study from the ADHB. Women who need induction of labour at term (37 weeks gestational age or more) will be asked if they are interested in participating by their own midwife or doctor. The research team will get in touch to provide more information and give you the opportunity to answer questions.

For you to participate in the study, you will need to meet certain criteria (we call these inclusion and exclusion criteria). You will also need to sign this consent form if you wish to participate. This form contains information on the study as well as particulars regarding our study procedures.

Your participation is voluntary (your choice). If you don't want to take part in this study, you don't have to. You will receive the best possible care whether you take part or not.

This study is partially funded through the University of Auckland. We will be seeking more support to carry out the study. The lead investigator, Meghan Hill, MBBS, MS, has a joint appointment with the University of Auckland and the ADHB. Her contact details are at the end of this form.

This study has been approved by the Northern A Health and Disabilities Ethics Committees (HDEC) and also by the ADHB locality.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You have been chosen to participate as you are presenting for an induction of labour at ≥37 weeks gestational age.

If you choose to participate in the study, you will sign the consent form at the end of this document. When you are examined and found to be physically ready for an infusion of oxytocin (a medication that causes contractions) and potentially an ARM, you will be

allocated by chance to have an Early ARM or a Late ARM. This ARM procedure is what we perform during an induction of labour when patients are going to receive oxytocin as an infusion. The timing of ARM can be individualized and different people perform it at different times during an induction of labour. At this hospital, the usual practice has been to perform an Early ARM, though not everyone does this as routine. Oxytocin is the most commonly used medication for labour induction. We give this medicine to you via an intravenous catheter. It causes contractions and the intention is that it causes you to go into labour. There are several small studies regarding whether it is better to perform an Early ARM or a Late ARM during induction of labour. However, mainly because of the small size of the studies, it is still unknown which approach is better. This is the reason for performing this study.

Participants who are allocated to Early ARM will have their ARM performed within 60 minutes (either before or after) oxytocin is started.

Participants who are allocated to Late ARM will have their ARM performed either when their cervix is 6cm or more dilated, or when they have been on oxytocin for 12 hours, whichever comes first.

After you have had your baby, the research team will collect information from the medical record regarding your labour process, the delivery of your baby and any other relevant pieces of information (for example any laboratory/pathology results related to your admission to have your baby).

The time commitment for you involves the time it takes to discuss the study, read the consent form and be able to come to a decision about whether you want to participate or not. For most women this will be 30-60 minutes. There are no follow up visits required on your part after participation in this study. However, while you are still in hospital after your birth, we will ask you to complete a survey about your experience. If you leave the hospital quickly after having your baby, we may contact you by phone to ask you the questions in the survey.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

The only benefit to you from being in this study would be knowing that you participated in research that may contribute to our understanding of how to most effectively and safely perform inductions of labour.

Though having a baby in modern times is quite safe for both women and their babies, there are risks to giving birth. They include minor risks, like getting bruising at an intravenous catheter site, to major risks, like bleeding heavily after the birth. These risks can occur whether you are participating in a study or not. Though this study is designed to see if infections and other complications are more or less likely in one group or another, this is not something we know (and the reason we are doing the study). For this reason, we wouldn't say that the study would place you at any risk over the risk of having a baby.

We would not expect you to be upset or distressed as a result of participating in the study. However, if you change your mind and want to withdraw from the study, you may speak to a member of the research team and do this. In this situation we could also arrange additional support for you.

There is a small risk of loss of confidentiality regarding your private health information. There is more about this later in the form, including the protections in place to prevent this from happening.

WHO PAYS FOR THE STUDY?

You will not incur any costs as a result of participating in this study. You will also not be paid to participate.

WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

WHAT ARE MY RIGHTS?

Participation in this research is completely voluntary. You are free to decline to participate or agree and then change your mind and withdraw from the research. This will not result in any change in the quality of the care that you receive.

If you would like to access information collected about you as part of this study, you may contact the Lead Investigator, Meghan Hill, MBBS, MS. Her contact details are at the end of this form.

We do not anticipate any new information relevant to this study during the time we are performing it. However, if there is new, relevant information, we will inform you.

We take several precautions to protect your privacy and confidentiality. We will not discuss this study with you in a space that is not private. We will keep your information (consent forms, clinical data sheets, study survey) in a locked cabinet within a locked office area. Any data collected about you during this study will be stored with a unique study number that is allocated to you. This data will be stored on a password-protected database. Only the researchers will have access to this database and only the researchers will be able to link your study number to your NHI.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

Should you choose to participate in the study but then change your mind and withdraw from the study we will ask if we may continue to collect your information, while not performing your ARM at the prespecified time. If you are willing to do this we will still collect your information but will leave the timing of your ARM up to the clinical team caring for you. If you would like to withdraw from the study entirely, please contact the Lead Investigator, Meghan

Hill, MBBS, MS, whose details are at the end of this form. If the study analysis has already been performed, you will not be able to withdraw from the study.

We will keep your data for 10 years after the completion of the study. After 10 years has gone by, we will delete your data. It is possible that during this time, we may look at the data to see if there are other relevant things about clinical care that impact outcomes from induction of labour. This is called 'future use' of data. If we decided to do further analysis after the completion of this study, we would have to ask for ethical approval through the appropriate channels before we could do this research.

If you would like a copy of the study results, please indicate this on the consent form. You may also go to the website www.nationalwomenshealth.adhb.govt.nz and look under the heading "Programmes and Research". We anticipate that complete results will be available 2-3 years after we have started recruitment.

WHAT WILL HAPPEN TO MY INFORMATION?

During this study the researcher staff will record information about you and your study participation. This includes information about your labour, the timing of your ARM and the birth of your baby and any laboratory or pathology results. If needed, information from your hospital records and your GP may also be collected. You cannot take part in this study if you do not consent to the collection of this information.

IDENTIFIABLE INFORMATION

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). Only the researchers involved in this study will have access to your identifiable information. The only identifiable information will be; your completed consent form, clinical data sheet, your completed survey, the list that links your NHI to your unique study number/code.

DE-IDENTIFIED (CODED) INFORMATION

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the research team. Instead, you will be identified by a code. The researcher will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

The following groups may have access to your coded information:

- The research team
- Regulatory or other governmental agencies as required for an audit of this study, for example.

FUTURE RESEARCH USING YOUR INFORMATION

We do not intend to use your information for future research unrelated to the outcomes of this study. However, it is possible that after this trial is complete, we may look at the data of women who participated to see if there are other relevant things about clinical care that impact outcomes from induction of labour. This is called 'future use' of data. If we decided to do further analysis after the completion of this study, we would have to ask for ethical approval through the appropriate channels before we could do this research.

SECURITY AND STORAGE OF YOUR INFORMATION

Your identifiable information is held at the University of Auckland during the study. After the study it is transferred to a secure archiving site and stored for at least 10 years, then destroyed. Your coded information (with your study number) will be entered into electronic case report forms and uploaded into a dataset. This dataset will be used for us to combine the findings from all women who participate and look at overall outcomes. Coded study information will be kept by in secure, cloud-based storage indefinitely. All storage will comply with local and/or international data security guidelines.

RISKS

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

This research includes basic information such as your ethnic group, geographic region, age range, number of babies you have had and sex. It is possible that this research could one day help people in the same groups as you. However, it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatize, or discriminate against members of the same groups as you.

RIGHTS TO ACCESS YOUR INFORMATION AND RESULTS

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

You can request a letter telling you about the study results. The letter will be sent to you once the final study report is available (this can take 1 – 2 years). A description of this trial will also be available on the Australia New Zealand Clinical Trials Registry (ANZCTR) registry website, https://anzctr.org.au/. This website will not include information that can identify you. At most, it will include a summary of study results.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

Please ask if you would like to access the results of your screening and safety tests during the study.

If you have any questions about the collection and use of information about you, you should ask a member of the research team. You may also contact Meghan Hill, with contact details listed at the end of this form.

RIGHTS TO WITHDRAW INFORMATION

You may withdraw your consent for the collection and use of your information at any time, by informing your Study Doctor.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken.

OWNERSHIP RIGHTS

Information from this study may lead to discoveries and inventions or the development of a commercial product. The rights to these will belong to the study team. You and your family will not receive any financial benefits or compensation, nor have any rights in any developments, inventions, or other discoveries that might come from this information.

DATA-LINKING

In this study we will create a data set to keep information on participants without any specific identifying factors. We do this to protect your information. We will not be linking this dataset with any other data sets

DATABANK/REGISTRY

As part of this study, we will not be seeking to provide your details or data to a databank or registry.

USE OF NEW TECHNOLOGIES (E.G. ARTIFICIAL INTELLIGENCE, HEALTH APPS)

We will not be utilizing new technologies as a part of this research.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Name, position: Meghan Hill, MBBS, MS, Lead Investigator
Telephone number: 09-373-7599 x 87941
Email: meghan.hill@auckland.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone:	0800 555 050
Fax:	0800 2 SUPPORT (0800 2787 7678)
Email:	advocacy@advocacy.org.nz
Website:	https://www.advocacy.org.nz/

For Maori health support please contact :

Name, position: He Kamaka Waiora (Māori Health Team)
Telephone number 09 4868324 x 2324
Or
Name, position: Māori Research Advisor
Telephone number: 09 4868920 ext 3204.

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 38442 (0800 4 ETHIC)
Email: hdecs@health.govt.nz

Consent Form

If you need the assistance of an interpreter,
one can be made available either in person or by phone.

Please tick to indicate you consent to the following

Please only include yes/no boxes if the statement is truly optional (i.e – that a person could still participate if they answer no).

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.		
I have been given sufficient time to consider whether or not to participate in this study.		
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.		
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.		
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.		
I consent to the research staff collecting and processing my information, including information about my health.		
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.	Yes ☐	No ☐
I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.	Yes ☐	No ☐
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.		
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.		

I understand the compensation provisions in case of injury during the study.	
I know who to contact if I have any questions about the study in general.	
I understand my responsibilities as a study participant.	
I wish to receive a summary of the results from the study.	Yes ☐ No ☐

Declaration by participant:
I hereby consent to take part in this study.

Participant's name:

Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name:

Signature: Date: