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**Invitation to Participate in Research: Focus Group**

**Project:** OPTIMISing induction of labour care: oral misoprostol versus balloon dilatation within a stratified inpatient to outpatient setting [The OptiMis-IO study]: A feasibility study

**Ethics approval number:** *[105360]*

**Investigator team**

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| **Title**  | OptiMising induction of labour care: oral misoprostol versus balloon dilatation – Study 1 |
| **Short Title**  | *OptiMis-IO-1*  |
| **Principal Investigator**  | Dr Rachael Nugent   |
| **Co Investigators**   | Associate Professor Lauren Kearney Dr Jane Maher Dr Nigel Lee  Dr Xin Yu (Adeline) Foo  Dr Emma Seed Dr Christoph Lehner  Dr Tegan Triggs Dr Bec Jenkinson Associate Professor Emma Ballard  |
| **Location**  | [Insert on site specific PICF]   |

**Purpose**

The purpose of this study is to determine whether an alternative method of induction of labour (low-dose, oral misoprostol) is feasible, safe and acceptable to women within Australia. The way that labour is induced, when using low-dose, oral misoprostol is different to standard approaches, and as maternity care providers this may impact on how you work with women during this time.

**Participant Involvement**

We would like to understand your views and experiences of being involved in the OptiMis-IO study as a midwife or doctor. Participation in this study is voluntary and will involve participation in a single focus group. It is expected the session will take between 30-60 minutes, and will be conducted at a place and time suitable to you. The focus group will be guided by a facilitator whose role will be to facilitate discussion and ensure the smooth running of the topics of conversation.

**Risks and benefits**

There are no specific risks involved in focus group participation. While you will not receive any direct benefit for participating, your contribution to the process will provide a vital step in informing how we enhance the way we induce labour and implement changes to this in busy maternity units.

**Consent**

Consent to participate in this research project is indicated by signing the consent form. By signing the consent form you indicate that you understand what is involved in this research project and that you give your consent to participate in this focus group. Consent is for the use of your data and information in a re-identifiable format in this and future related research.

**Results**

The focus groups will be audio recorded and transcribed. The findings from the focus group will be thematically analysed and summarised into key these (or areas) of shared interest and understanding. Future results will be prepared as a manuscript for submission in a peer reviewed journal. You may request a summary of the results of this project by contacting the Chief Investigator. You will be offeredthe opportunity tohave your participation included in the acknowledgements of any publications arising from this study.

**What will be done to make sure my information is confidential?**

All data will be de-identified. This data will be securely stored, electronically, in password-protected documents. As there will be a small sample size (20-30 participants) there is a small chance the data from some activities may be linked to you. There is potential that de-identified data may be shared with future research teams upon request.

**Who should I contact for more information?**

If you would like more information about the project or if you need to speak to a member of the research team please contact:

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| **Name:** | Dr Rachael Nugent |  |
| **Phone:** | 0413 904 205 |  |
| **Email:** | Rachael.Nugent@health.qld.gov.au  |  |
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| **HREC Information:** The Metro North Health Human Research Ethics Committee (HREC) has approved this study. If you have any concerns and/or complaints about the project, the way it is being conducted as a research participant, and would like to speak to someone independent of the project, please contact the HREC Coordinator on:(07) 3646 5280 or email MetroNorthResearch-Ethics@health.qld.gov.au |
| **Local Governance Contact Information:** **Name:** **Email:**  |
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***The Researchers and the University and Health Services would like to thank you for your interest in this project and appreciate the effort involved.***

**Consent Form -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | OptiMising induction of labour care: oral misoprostol versus balloon dilatation – Study 1 |
| **Short Title** | OptiMis-IO-1 |
| **Project Sponsor** | SCHHS  |
| **Coordinating Principal Investigator/****Principal Investigator** | Dr Rachael Nugent  |
| **Associate Investigator(s)** | Associate Professor Lauren Kearney Dr Jane Maher Dr Nigel Lee  Dr Xin Yu (Adeline) Foo  Dr Emma Seed Dr Christoph Lehner  Dr Tegan Triggs Dr Bec Jenkinson Associate Professor Emma Ballard  |
| **Location**  |  |

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand. I understand the purposes, procedures and risks of the research described in the project.

I understand all information I provide will be kept confidential and not impact my current or future employment in any way. I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study. I understand that I will be given a signed copy of this document to keep.

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|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
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**Declaration by Study Doctor/Senior Researcher†**

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

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|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
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† A senior member of the research team must provide the explanation of, and information concerning, the research project. Note: All parties signing the consent section must date their own signature.

**Form for Withdrawal of Participation -** *Adult providing own consent*

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| --- | --- |
| **Title** | OptiMising induction of labour care: oral misoprostol versus balloon dilatation – Study 1 |
| **Short Title** | OptiMis-IO-1 |
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| **Coordinating Principal Investigator/****Principal Investigator** | Dr Rachael Nugent  |
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| **Location**  |  |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my employment, my relationship with those I work with at the Sunshine Coast Hospital and Health Service.

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|  | Name of Participant (please print) |  |  |  |  |
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|  | Signature |  |  Date |  |  |
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*In the event that the participant’s decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.*

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**Declaration by Study Doctor/Senior Researcher**

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|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
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