**Participant Information sheet**

Study title: Views and experiences of women and staff of outpatient induction of labour: a mixed methods study

Researcher: Lisa Smith (PhD student and Consultant Midwife)

IRAS ID: 240694 ERGO ID: 31461

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

**What is the research about?**

In 2015, University Hospital Southampton NHS Foundation Trust launched an outpatient induction of labour service for women having their first baby who are at low risk of complications. Women are invited into hospital between 10 and 12 days past their due date and following a check-up, a controlled-release dinoprostone vaginal pessary is inserted. Providing the check-up is normal, women are then discharged home for 24 hours after they have been given advice about when to contact the service again. The pessary stays in place until labour starts, waters break or it is removed by a member of staff.

There is little evidence about what women and staff think about women returning home during this time and so this research aims to find out more about women’s and staff views and experiences of outpatient induction of labour.

Participant recruitment and data collection will take place between February 2019 and January 2020.

**Who is conducting the study?**

Lisa Smith is conducting the research as part of a PhD at the University of Southampton. She is also a Consultant Midwife at the Trust.

**Why have I been asked to participate?**

You are eligible to take part in this research because:

* You are a midwife at UHS NHS Foundation Trust working in the midwifery led pathway and talk to women about outpatient induction of labour
* You are a midwife supporting women undergoing outpatient induction of labour
* You are a midwife working within the Labour Line telephone triage service
* You are an obstetrician involved in the care of women undergoing outpatient induction of labour

The researcher is aiming to recruit up to 12 members of staff and 12 women.

**What will happen to me if I take part?**

If you decide to take part this will involve having an interview lasting about 30-60 minutes with the researcher. You can choose whether you would like the researcher to come to your home, Princess Anne Hospital or the New Forest Birth Centre. Parking and mileage expenses will not be reimbursed, however there are no parking charges at the New Forest Birth Centre. On the day of the interview you will be asked to read and sign a consent form prior to being asked some questions about your views and experiences of talking to women about or caring for women undergoing outpatient induction of labour.

**Are there any benefits in my taking part?**

There may not be any direct benefits to you in taking part but it may increase your understanding of how research is undertaken. We hope the findings of the study may help improve care for women undergoing induction of labour.

**Are there any risks of taking part?**

There are no risks involved in taking part in the interview. In the unlikely event you feel upset during the interview, you will have the opportunity to stop at any time if you do not wish to continue. Similarly, the researcher may decide to stop the interview if you appear to be distressed. The researcher can direct you to sources of support such as the Trust’s Employee Assistance Programme or your Professional Midwifery Advocate.

**What data will be collected?**

In line with the EU General Data Protection Regulation (GDPR) it is important that the researcher is fair and transparent about how data about you is collected and processed.

Data will be collected during the interview about your views and experiences of talking to women about or caring for women undergoing outpatient induction of labour. If you give consent, this will be in the form of an audio recording. If you decline the interview being recorded, the researcher may ask to make notes.

Some personal data is defined as special category data by the Data Protection Act (1998). This includes information on ethnicity, sexual orientation, gender identity, religious beliefs, genetic data or biometric data from which you can be uniquely identified and health data. Information of this nature disclosed during the interview will be anonymised.

**Will my participation be confidential?**

Your participation and the information we collect about you during the course of the research will be kept strictly confidential.

At the beginning of the interview you will be given a unique participant code to act as a pseudonym to protect your confidentiality. During the research process it is important to be able to link your participant code with your personal data (your name and telephone number). An example of when this would be required would be if you wish to withdraw from the study. In this example, being able to link your participant code with your personal data would enable the researcher to retrieve and then destroy the correct interview data. However, to protect your confidentiality, the data file which contains both your personal information and your participant code would be stored securely in a separate password protected file to the interview data.

Only the researcher and responsible members of the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

If you give consent to the interview being audio-recorded, the device will be transported securely then the recording will be transcribed. The data file of the transcription will be stored securely in a password protected folder within the University of Southampton computer network and the original audio recording will then be deleted.

Your data will only be accessed by the researcher and will be stored securely and destroyed after 10 years following University guidelines.

Short quotes from your interview may be included in publications but by using a unique participant code to act as a pseudonym you would not be identifiable by others.

**Do I have to take part?**

No, it is entirely up to you to decide whether or not to take part.

**Making a decision to take part in the research study**

If you decide you would like to take part, or if you would like some more information before making a decision, please email Lisa Smith (lisa.smith@uhs.nhs.uk) to arrange a no-obligation discussion. Following this, if you decide you would like to take part in the research study, an appointment will be made for a 30-60 minute interview at a mutually convenient time. You will have a further opportunity to ask any questions about the research study before the interview and will be asked to read and sign a consent form to confirm you have agreed to take part.

**What happens if I change my mind?**

You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights being affected. You can contact the researcher or the project supervisors. If you withdraw from the study, any data collected about you, such as your interview transcript, will be deleted.

**What will happen to the results of the research study?**

Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent.

The findings of the research will be submitted for publication in academic journals. If you would like a copy of any findings please let the researcher know.

**Protecting women’s health**

The researcher has a professional responsibility to challenge any poor practice identified during data collection in accordance with the NMC Code. This would involve a discussion to explore any learning from the incident as well as observing Trust risk management procedures. This may include submitting an adverse incident form and a wider Trust review of what happened.

**Where can I get more information?**

Please email lisa.smith@uhs.nhs.uk if you would like to take part or learn more about the research.

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| **Researcher**Lisa SmithConsultant MidwifeBroadlands Birth CentrePrincess Anne HospitalCoxford RoadSouthamptonSO16 5YAlisa.smith@uhs.nhs.ukls1r15@soton.ac.uk | **Supervisor**Dr Elizabeth CluettLead Midwife for EducationDirector of Practice Projects Building 67Faculty of Health SciencesUniversity of SouthamptonSouthamptonSO17 1BJe.cluett@soton.ac.uk  | **Supervisor**Dr Julie CullenHead of Nursing Midwifery and Health, Faculty of Health SciencesBuilding 67Faculty of Health SciencesUniversity of SouthamptonSouthamptonSO17 1BJ*j.cullen@soton.ac.uk* |

**What happens if there is a problem?**

If you have a concern about any aspect of this study, you should speak to the researcher who will do their best to answer your questions.

If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

If you have a complaint about any aspect of your employment which has not been resolved by your line manager or the Director of Midwifery and Professional Lead for Neonatal Service, please contact Human Resources on 023 8120 4446 or your Trade Union Representative.

**Data Protection Privacy Notice**

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, ‘Personal data’ means any information that relates to and is capable of identifying a living individual. The University’s data protection policy governing the use of personal data by the University can be found on its website (<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at <http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf>

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University’s policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason (‘lawful basis’) to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the ‘Data Controller’ for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information linking you with the unique participant code given to you for 10 years after the study has finished after which time any link between you and your information will be removed. This identifiable information can only be accessed by the researcher.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University’s data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University’s Data Protection Officer (data.protection@soton.ac.uk).

**Who has reviewed this research?**

The study has been approved by the NHS ethics committee and the University of Southampton.

**Who is organising and funding the research?**

PhD fees funded by Health Education Wessex as part of the Trainee Consultant Practitioner Programme 2015-18.

**Thank you for taking the time to read this information sheet.**