Health
South Western Sydney
Local Health District

Participant Information Sheet/Consent Form

Bankstown Hospital

Title	**S**elf – **C**reated **R**ecords by **E**APP for **E**arly a a**N**tenatal hospital access
Short Title	SCREEN A
Protocol Number	*2020/ETH02171*
Principal Investigator/ Principal	Dr Angela Makris
Location	*Bankstown Hospital*

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project - SCREEN. This is because you are booking- in to the hospital for your pregnancy care.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

By continuing on and answering the questions in the survey, you are opting to take part in the research project. By opting to take part, you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to the tests and research that are described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information Sheet to keep.

2 What is the purpose of this research?

We are asking you to trial a new way of booking in to the hospital for your pregnancy. The new way, is to complete an online survey of your and your partners health issues. We want to see if the new way is as good as the current way of booking-in to the hospital- your visit with the midwife.

This research has been initiated by the study doctor, Dr Angela Makris

3 What does participation in this research involve?

By agreeing to participate you will be asked to answer some questions about your and your partner's health relating to this pregnancy. The new way of booking in will assess any risks to your pregnancy and let you know what they are based on your answers to the questions. A copy

of your answers and the risks will be emailed to you at the end of the survey. You will also be asked a 4 questions at the end about your experience completing the survey online.

We will compare this information, to the information from your midwife visit. We will also collect information about how your pregnancy went from the medical records.

There are no costs associated with participating in this research project, nor will you be paid.

4 What do I have to do?

Complete the survey on the I-pad provided about your health and the questions at the end about your experience.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with *Liverpool Hospital.*

6 What are the possible benefits of taking part?

You will not receive any benefits from participating in this research, however possible benefits may include *helping us improve our pregnancy survey and the way women book-in to the hospital.*

7 What are the possible risks and disadvantages of taking part?

If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

This research project involves the collection of information about your use of drugs.

8 What if I withdraw from this research project?

If you decide to withdraw from this research project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

9 Could this research project be stopped unexpectedly?

Although highly unlikely, this research project may be stopped unexpectedly for a variety of reasons. These may include *complete city wide pandemic lockdown.*

10 What happens when the research project ends?

Once the study in complete, we will be advertising the results on the hospital Womens Health webpage at: https://www.swslhd.health.nsw.gov.au/ as well as the WHITU Facebook page (Whitu Swslhd). We expect this research to take about 12 months to complete.

Part 2 How is the research project being conducted?

11 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Only the research staff will have access to your data. All the data stored about you will not be linked to you by name, but rather you will be allocated a random code. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.
Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the research team accessing health records if they are relevant to your participation in this research project.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Individual patient data will never be presented only group data of all the women together.

12 Compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

13 Who is organising and funding the research?

This research project is being conducted by *Dr Angela Makris and is being funded by WHITU (Women's Health Initiative Translational Unit). WHITU is a research group of clinicians and academic based in the SWSLHD.*

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

14 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of *South West Sydney Local Health District.*

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

15 Further information and who to contact

The person you may need to contact will depend on the nature of your query.
If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on *02 8738 3788* or any of the following people:

Clinical contact person

Name	*Gaksoo Lee*
Position	*Research Midwife*
Telephone	*0436 932 004*
Email	*Gaksoo.lee@health.nsw.gov.au*

21. Complaints contact person

This study has been approved by the South Western Sydney Local Health District Human Research Ethics Committee. Any person with concerns or complaints about the conduct of this study should contact the Research and Ethics Office, Locked Bag 7103, LIVERPOOL BC NSW 1871 on 02 8738 8304 / fax 02 8738 8310 / email SWSLHD-ethics@health.nsw.gov.au, website: http://www.swslhd.nsw.gov.au/ethics/default.html and quote 2020/ETH02171.

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.