Participant Information Sheet/Consent

Title	Syphilis in pregnant women and their newborn infants in Queensland 2014-2018: assessment of outcomes and evaluation of barriers to care	
Short Title	SiPN	
Protocol Number	6.0	
Project Sponsor	Queensland Department of Health	
Coordinating Principal Investigator	Dr Clare Nourse	Queensland Children's Hospital
Co-Investigator(s)	Dr Mandy Wu	Queensland Children's Hospital
	Dr Sumudu Britton	Royal Brisbane and Women's Hospital
	Dr Mandy Seel	Metro North Hospital and Health Service
	Dr Paul Griffin	Mater Misericordiae
	Dr Judith Dean	The University of Queensland
	Mr James Fowler	The University of Queensland
Location	Royal Brisbane and Women's Hospital Mater Misericordiae Metro North Public Health Unit Queensland Children's Hospital Metro South Hospital and Health Service West Moreton Hospital and Health Service Gold Coast Hospital and Health Service Caboolture Hospital	

Part 1 What does my participation involve?

Researchers from the University of Queensland, in partnership with Queensland Children's Hospital, Mater Misericordiae, Royal Brisbane and Women's Hospital and Metro North Hospital and Health Service are undertaking a mixed methods research project assessing and evaluating the management of syphilis detected in women in pregnancy, the follow up of the infant's health outcomes and the barriers to appropriate management of the illness.

1 Introduction

You are invited to take part in an interview to share your experiences and thoughts about the management of congenital syphilis.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the processes involved with taking part. 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 health worker.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
- Understand what you have read
- Consent to take part in the research project
- Consent to be involved in the research described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

This study aims to describe the management of pregnant women with positive syphilis serology in South East Queensland and identify facilitators and barriers to optimal management of congenital syphilis in women and their infants.

This research has been funded by the Queensland Sexual Health Research Fund, administered on behalf of Queensland's Department of Health by the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine.

This research is being conducted in collaboration with investigators from the Queensland Children's Hospital, Royal Brisbane and Women's Hospital, Metro North Public Health Unit, Mater Misericordiae and the University of Queensland.

The research has been initiated in collaboration with all listed investigators.

3 What does participation in this research involve?

Participation in this research will involve a semi-structured interview conducted by members of the research team from UQ. The interview will take approximately 30 to 60 minutes at a place and time most convenient to you.

During the interview, you will be asked questions about your experiences and opinions – there are no correct answers to the questions we will ask and you are free to answer or not. You can choose to not answer any question. The researchers have no legal obligation of disclosure regarding any information you provide.

As part of the interview, you will be asked to provide details such as your age, gender, length of time working as a healthcare professional and your syphilis screening protocols and processes. This information will be de-identified to ensure confidentiality and only used to broadly describe the profile of people participating in the study.

The interviews will be digitally recorded, with your consent, so we can accurately capture what you say. Providing consent tells us you have read this form and understand that you consent or the interview to be recorded. You can also request to review the transcripts for accuracy.

There are no costs associated with participating in this research project, you will receive a $150.00 gift card following the interview as a token of appreciation of your time.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids researchers or participants jumping to conclusions.

4 Other relevant information about the research project

This phase of the project will be conducted collaboratively over approximately 4 study sites with up to 50 participants. All interviews will be conducted individually.

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 relationship with research staff or their affiliated institutions.

6 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, your participation will go on to contribute to future recommendations and management of congenital syphilis in Australia.

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

The risks inherent in this study design are minimal. The primary risk involved in participating in this study is related to the confidentiality of the information provided.

Care will be taken to ensure you are able to share you experience in a safe and comfortable environment.

8 What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time without comment or penalty. If you decide to withdraw from the 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, you will be asked to complete and sign a 'Revocation of Consent' form; this will be provided to you by the research team.

If you decide to leave the research project, the researchers will not collect additional personal information from you..

If you withdraw from the interview, the digital recording of the interview will be deleted in full at the time you withdraw from the study. No information collected from you will be included in the data transcription, analysis or in any study output.

9 Could this research project be stopped unexpectedly?

This research project is not foreseen to be stopped unexpectedly.

10 What happens when the research project ends?

The project will be completed once all relevant and necessary data has been collected or at the completion of the funding period.

Part 2 How is the research project being conducted?

11 What will happen to information about me?

The digital recording of the interview will be transcribed by experienced transcribers from a transcription company who have undergone training on the ethical issues associated with the project and has an ongoing contractual relationship with UQ researchers on a range of research projects being undertaken. The transcribers will sign a confidentiality agreement before commencing transcribing.

Any identifiable information digitally recorded will be altered to ensure confidentiality. The only identifiable information will be on the consent form that will be stored separately and securely in a locked cabinet in a locked facility to which only the UQ researchers will have access.

By signing the consent form you consent to the research team 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.

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.

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. The information will remain de-identified throughout all publication processes.

In accordance with relevant Australian and/or Queensland privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

12 Complaints and compensation

If you suffer any distress or psychological injury as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support.

13 Who is organising and funding the research?

This research project is being conducted by researchers from Queensland Children's Hospital, Royal Brisbane and Women's Hospital, Metro North Public Health Unit, Mater Misericordiae and the University of Queensland. Information for this phase of the project that you will participate in will be gathered by members of the research team from the University of Queensland.

This study is funded by the Queensland Sexual Health Research Fund. You will receive a $150.00 gift card following the interview as a token of appreciation of your time.

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 Metro North Hospital and Health Service.

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 problems which may be related to your involvement in the project or any complaints you may have, you can contact the following people:

Co-Investigator #1: Dr Judith Dean
Senior Research Fellow
School of Public Health, The University of Queensland
288 Herston Road, HERSTON QLD 4006
E: j.dean4@uq.edu.au P: +61 7 3346 4876

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	tro North Hospital and Health Service Human Research Ethics mmittee – Royal Brisbane and Women's Hospital
HREC Executive Officer	n-Maree Gordon
Telephone	) 3646 5490
Email	WH-Ethics@health.qld.gov.au

Consent Form

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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 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 project without affecting my future care.

I understand that I will be given a signed copy of this document to keep.

- ☐ I want to participate in this project.
- ☐ I want to have my contact details recorded so that UQ researchers can contact me.
- ☐ I want to be contacted at a later date for study updates.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by 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.

Name of Researcher† (please print) _____

Signature _____ Date _____

† An appropriately qualified 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.