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UTS
UNIVERSITY OF TECHNOLOGY SYDNEY

PARTICIPANT INFORMATION SHEET

UTS HREC Approval Reference Number: ETH19-3718

The development of a core outcome set for studies on vasa previa in pregnant women

WHO IS DOING THE RESEARCH?

My name is Nasrin Javid and I am a researcher at the Faculty of Health, University of Technology Sydney. I am working with Professor John Kingdom and Dr. Rohan D'Souza (both Maternal-Fetal Medicine Specialists at the University of Toronto, Canada), and Dr. Natasha Donnolley from the University of New South Wales, Australia and the International Vasa Previa Foundation.

I would like to invite you to participate in this research. Before you decide whether you want to participate, it is important that you read this Participant Information Sheet carefully. Ask questions if there is anything that is not clear or you would like to receive more information. You may also like to discuss this with others before you participate.

WHAT IS THIS RESEARCH ABOUT?

Vasa previa is a rare, under-researched condition that is associated with perinatal mortality. Despite advances in maternity care, there is still little consensus regarding the diagnosis and management of this condition in women. There is also little known about the research outcomes that are considered important by pregnant women, their families, and stakeholder groups, including healthcare providers, researchers, and policymakers.

The aim of this research is to explore what outcomes are considered important by women who have been affected by vasa previa as well as other stakeholders who have experience with this condition, what outcomes should, therefore, be included in all research studies within this area.

The information from this study will guide the development of a survey to develop core outcome sets for vasa previa so that all studies on vasa previa use the same outcomes that can be compared and combined improving our understanding of how to best manage this condition.

WHY HAVE I BEEN ASKED?

I am inviting obstetricians, midwives, obstetric nurses, neonatologists, ultrasonographers, researchers, guideline developers and policymakers around the world to participate in this research. You can participate in this study if:

- You are working as a clinician, researcher, policy maker, guideline developer, and
- Have cared for a woman with vasa previa or been involved in research, policy or guideline in relation to vasa previa.

IF I SAY YES, WHAT WILL IT INVOLVE?

If you decide to participate, you will be given this information sheet to keep and will be asked to sign a consent form. I will discuss the interview procedure with you and organise a time to interview you on the phone.

The interview will take around one hour, at a time that is mutually agreed and convenient for you. With your consent, the interview will be digitally voice recorded to allow accurate transcription of your responses. The interview will be semi-structured and based on your views regarding the research outcomes that you think are important for women with vasa previa, but will be flexible to meet your needs.

DO I HAVE TO SAY YES?

Participation in this research is entirely voluntary. It is completely up to you whether or not you decide to take part.

WHAT WILL HAPPEN IF I SAY NO?

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason, by contacting Nasrin Javid on Nasrin.javid@uts.edu.au and signing a 'withdrawal of consent' form. I will thank you for your time and will not contact you about this research again. The data collected up to the time you withdraw will form part of the research results. If you do not want your data to be included in this study, you must tell the researcher when you withdraw from this study.

WHAT ARE THE EXPECTED BENEFITS?

There is no direct benefit for you to participate in this study. You may feel satisfied as a result of participating in this research, which aims to help to optimise the pregnancy care of women with vasa previa.

ARE THERE ANY RISKS/INCONVENIENCE?

Minimal risks have been identified. It is possible that you experience some inconvenience as you will give around one hour of your time to participate in this interview. To minimise the inconvenience, we will conduct the interview on the phone or online, and at a time that is convenient for you.

You may feel distressed talking about your experience during the interview. The researcher who will conduct the interviews is a senior clinical midwife who has provided care for pregnant women and their partners and babies for around 20 years and has extensive experience in caring for women with high-risk pregnancies. You will be advised to contact counselling services or other relevant support services in your area if needed. The researcher will discuss possible avenues for support should that be necessary.

No identifiable information will be collected on the women you have cared for or the hospitals you have worked in. Any potentially identifiable information regarding the women you have cared for or the hospital will be removed from the transcripts before the data analysis. Any information that is obtained in connection with this study and that can be identified with you or the organisation you work will remain confidential and will be disclosed only with your permission, except as required by law. No identifiable information will be reported.

CONFIDENTIALITY

By signing the consent form, you consent to the research team collecting and using personal information about you for the research project. All this information will be treated confidentially. Any identifiable information will only be known to the researcher conducting the interview. After the interview the data will be transcribed, and your name and any other potentially identifiable information will be taken out from the transcript and replaced by a pseudo name. All data for analysis will be anonymised.

The findings from this study will be presented at conferences and published in an academic journal(s). No identifiable information will be presented in any conference or publication. To ensure anonymity and confidentiality, you will only be known to the researcher(s) conducting the interview and the rest of the research team will be blinded to your name.

WHAT TO DO NEXT IF YOU WOULD LIKE TO TAKE PART IN THIS RESEARCH?

It is important that you read this information sheet carefully and contact me on +61411245756 or Nasrin.javid@uts.edu.au if there is anything that is unclear or you need more information. If you decide to participate, you will then sign a consent form, and participate in an interview that will take around one hour.

WHO HAS FUNDED AND APPROVED THE STUDY?

Funding has been received from the Perinatal Society of Australia and New Zealand as well as the International Vasa Previa Foundation. The study has been approved by the Human Research Ethics Committee of the University of Technology Sydney. *(UTS HREC Approval Number ETH19-3718).*

WHAT IF I HAVE CONCERNS OR A COMPLAINT?

If you have concerns about the research that you think I can help you with, please feel free to contact me on ph: +61 411 245 756, or email Nasrin.javid@.uts.edu.au

This study has been approved in line with the University of Technology Sydney Human Research Ethics Committee (UTS HREC) guidelines. If you have any concerns or complaints about any aspect of the conduct of this research, please contact the Ethics Secretariat on ph.: +61 2 9514 2478 or email: Research.Ethics@uts.edu.au and quote the UTS HREC reference number (ETH19-3718). Any matter raised will be treated confidentially, investigated and you will be informed of the outcome.

You will be given a copy of this form to keep.

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CONSENT FORM

(UTS HREC Approval Reference Number: ETH19-3718)

The development of a core outcome set for studies on vasa previa in pregnant women

I,……

[participant's name] agree to participate in the research project *"The development of a core outcome set for studies on vasa previa in pregnant women"* which has been approved by the University of Technology Sydney Human Research Ethics Committee (UTS HREC reference number ETH19-3718) being conducted by Nasrin Javid, Nasrin.javid@uts.edu.au, phone: +61 411 245 756 of the University of Technology Sydney. I understand that funding for this research has been provided by Perinatal Society of Australia and New Zealand (PSANZ) and the International Vasa Previa Foundation.

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 as described in the Participant Information Sheet.

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 without affecting my relationship with the researchers or the University of Technology Sydney.

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

□ I agree to be audio recorded.

□ I agree that the research data gathered from this project may be published in a form that does not identify me in any way.

I am aware that I can contact Nasrin Javid on Nasrin.javid@uts.edu.au if I have any concerns about the research.

……	…….	_____/_____/_____
Signature (participant)	Please PRINT name	Date

NOTE: This study has been approved by the University of Technology Sydney Human Research Ethics Committee. If you have any complaints or reservations about any aspect of your participation in this research which you cannot resolve with the researcher, you may contact the Ethics Committee through the Research Ethics Officer (Ph: +61 2 9514 9772 Research.Ethics@uts.edu.au) and quote the UTS HREC reference number (ETH15-0137). Any complaint you make will be treated in confidence and investigated fully and you will be informed of the outcome.