ROYAL HOSPITAL FOR WOMEN
PARTICIPANT CONSENT
INFORMATION SHEET AND CONSENT FORM

CLINICAL RESEARCH

Automated Fetal Cardiac Function Parameters in Congenital Heart Disease (Evaluating heart function of the unborn baby using ultrasound in normal pregnancies and pregnancies complicated by congenital heart defects)

Patient information statement for complicated pregnancies

Invitation

You are invited to participate in a research study into the ultrasound evaluation of fetal (unborn baby) heart function in normal pregnancies and pregnancies complicated by congenital heart disease (heart defect).

The study is being conducted at the Royal Hospital for Women by:

- Professor Alec Welsh, Professor of Maternal-Fetal Medicine, Royal Hospital for Women and Head of the Perinatal Imaging Research Group, University of New South Wales.
- Professor Tracie Barber, Mechanical Engineer, University of New South Wales.
- Dr Anna Erenbourg, PhD Candidate, School of Clinical Medicine, University of New South Wales.

The study is part of an international collaborative study coordinated by Australian researchers listed above.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. What is the purpose of this study?

The purpose is to investigate fetal heart function. Babies are assessed in the womb using ultrasound, either with black and white pictures looking at structure or with colour (Doppler) to look at blood flow. Ultrasound is now being used more to look at how the heart works (functions) to help with clinical decision-making.

This can include taking measurements of blood flow across the main heart valves (such as a test called the Myocardial Performance Index or MPI) or using four-dimensional ultrasound using a technique called STIC.

The MPI might be useful for complicated pregnancies such as complicated twins sharing a placenta, or babies that aren't growing well, or when the mother has preeclampsia. In this study we would like to explore the value of these fetal cardiac parameters in normal pregnancies and pregnancies affected by heart defects.

This study forms part of Dr Erenbourg's PhD research.

2. Why have I been invited to participate in this study?

You are eligible to participate in this study as your baby has been diagnosed with a congenital heart disease, and you are having ultrasounds to monitor the health of the baby.

3. What if I don't want to take part in this study, or if I want to withdraw later?

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

New information about the MPI and STIC, or other techniques being studied may become available during the course of the study. You will be kept informed of any significant new findings that may affect your willingness to continue in the study.

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. Should you wish, your individual de-identified data may be withdrawn from this study.

4. What does this study involve?

If you agree to participate in this study, you will be asked to sign the Participant Consent Form.

If you decide to take part in the study, you will be asked questions related to your pregnancy and medical history. The study includes taking some extra ultrasound measurements at the time of your clinically indicated ultrasound scans. How often you

are having ultrasounds will differ depending on the fetal heart defect affecting your baby and the baby's general clinical conditions.

Taking part in the study requires additional evaluation of some heart functional parameters to the standard cardiological examination. The assessment of these parameters will be performed during one or two of your routine ultrasound evaluations, without interfering with the normally scheduled heart follow-up of your baby.

At the time of your ultrasound scans, a general wellbeing ultrasound will be performed (including fetal growth, amniotic fluid volume and routine blood flows), and then images of the heart movements and blood flow in the heart will be stored to be evaluated after you leave. The total time for this scan is likely to be approximately 40 minutes, of which approximately 25 will be for research. You will be given a report indicating your baby's weight and blood flows. At the end of the assessment, you will be given a report indicating your baby's general wellbeing. Research measurements will not be included in the report. In the rare unfortunate event that the research ultrasound detects a previously unknown problem, or if any other concerns come up, there will be the opportunity to discuss these with an obstetrician. An appointment will be booked for you with your treating Doctor or care provider who will appropriately discuss this with you and appropriate follow-up care will be organised.

The ultrasound machine we use will either be a clinical machine, or it may be a machine specifically designed for research scanning only. The research ultrasound machine is fully approved for research imaging, therefore any images generated from this machine will only be used for the purpose of this research project and not for diagnosis. A single machine will be used for your visit.

There is no need for any additional tissue or blood samples or any restriction on your lifestyle during the study. In addition, the researchers would like to have access to your medical record to obtain information relevant to the study. This includes collecting some routine information about your baby after birth, particularly your baby's birth weight and whether your baby had any complications in the first few days after birth. This information is collected to be compared with the ultrasound results and help us decide whether the ultrasound measurements are useful to clinicians monitoring complicated pregnancies. This study will be conducted over a 5-year period.

5. How is this study being paid for?

Ultrasound equipment used in the study has been purchased using research grant funding from the University of New South Wales and the Royal Hospital for Women Foundation. The time of the researchers is unpaid and forms part of the doctoral (higher research degree) work of Dr Erenbourg. No money is paid directly to individual researchers.

6. Are there risks to me in taking part in this study?

All medical procedures involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. In spite of all reasonable precautions, you might develop medical complications from participating in this study. The known risks of this study are that some women may feel faint or unwell when lying down for ultrasounds. If you feel unwell at any time during these tests, please let the person performing the test know straight away so that we can stop the test and change your position to help you feel better. There are no known risks to the baby of prenatal ultrasound, either of the routine ultrasound used to monitor unborn babies or of the research measurements used in this study. We will let you know if information comes out that may affect your choice about the study.

7. What happens if I suffer injury or complications as a result of the study?

If you suffer any injuries or complications as a result of this study, you should contact the study doctor as soon as possible, who will assist you in arranging appropriate medical treatment.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is caused by the procedures, or by the negligence of any of the parties involved in the study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

8. Will I benefit from the study?

This study aims to further medical knowledge and may improve future treatment of pregnancies affected by congenital heart diseases, however it will not directly benefit you.

9. Will taking part in this study cost me anything, and will I be paid?

Participation in this study will not cost you anything, and you will not be paid.

10. How will my confidentiality be protected?

Of the people treating you, only the study researchers named above or necessary others e.g. medical staff involved in your care will know whether or not you are participating in this study.
Engineers from UNSW will collaborate with Anna Erenbourg to run the image analysis by the automation algorithms, so they will need to have access to your anonymized ultrasound images. A statistician from UNSW statistical Department will help and

support Anna Erenbourg to analyze outcomes data, so they will have access to your anonymized data. Because the images and data are 'anonymized' these people will not know who you are and will have no way of identifying you.

Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researchers named above will have access to your details and results that will be held securely at the School of Clinical Medicine, Royal Hospital for Women.

11. What happens with the results?

If you give us your permission by signing the consent document, we plan to present the results at conferences or other professional forums and publish the results in peer-reviewed journals. In any presentation or publication, information will be provided in such a way that you cannot be identified. Any public information will describe group outcomes rather than individual results.

If you wish, a plain English summary of study results will be provided to you by your study doctor when the trial is finished, and data analysed upon specific request. Overall results of this study will be published in a medical journal allowing all health professionals to have access to the findings.

12. What should I do if I want to discuss this study further before I decide?

When you have read this information, the researcher will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact Professor Alec Welsh via email alec.welsh@unsw.edu.au or by calling (02) 9382 6214.

13. Who should I contact if I have concerns about the conduct of this study?

This study has been approved by the South Eastern Sydney Local Health District Human Research Ethics Committee. Any person with concerns or complaints about the conduct of this study should contact the Research Support Office which is nominated to receive complaints from research participants. You should contact them on 02 9382 3587, or email SESLHD-RSO@health.nsw.gov.au and quote 2022/ETH00943.

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.

ROYAL HOSPITAL FOR WOMEN
CONSENT FORM

Automated Fetal Cardiac Function Parameters in Congenital Heart Disease (Evaluating heart function of the unborn baby using ultrasound in normal pregnancies and pregnancies complicated by congenital heart defects)

1. I,.....
of.....
agree to participate in the study described in the participant information statement set out above.

2. I acknowledge that I have read the participant information statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.

3. I agree that medical record information about my infant(s) at birth may be collected and used for the purposes of this study.

4. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation, and I have received satisfactory answers.

5. I understand that I can withdraw from the study at any time without prejudice to my relationship to the **Royal Hospital for Women.**

6. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

7. I understand that if I have any questions relating to my participation in this research, I may contact Professor Alec Welsh on 02 9382 6214, or via email alec.welsh@unsw.edu.au, who will be happy to answer them.

8. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.

Complaints may be directed to the Research Ethics Secretariat, South Eastern Sydney Local Health District, Prince of Wales Hospital, Randwick NSW 2031 Australia (phone 02-9382 3587, fax 02-9382 2813, email SESLHD-RSO@health.nsw.gov.au.

Signature of participant	**Please PRINT name**	**Date**
Signature of witness	**Please PRINT name**	**Date**
Signature of investigator	**Please PRINT name**	**Date**

ROYAL HOSPITAL FOR WOMEN

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REVOCATION OF CONSENT

I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the Royal Hospital for Women or my medical attendants.

Signature of participant	**Please PRINT name**	**Date**
_____	_____	_____

The section for Revocation of Consent should be forwarded to Professor Alec Welsh, School of Clinical Medicine, Level 0, Royal Hospital for Women, Barker St, Randwick 2031.