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## WHĀNAU PARTICIPANT INFORMATION SHEET

**Full Study Title:** Why do outcomes of critical congenital heart disease in New Zealand differ by ethnicity?

**Short Study Title:** ECHO - Examining Congenital Heart Outcomes

**Sponsor:** The University of Auckland

**Lead Researcher:** Dr Simone Watkins

**Study Site:** Liggins Institute

**Contact phone number:** 09 923 6691 or 027 342 5811

**Ethics committee ref.:** 21/CEN/128

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You are invited to take part in a study on *why outcomes of critical congenital cardiac disease in New Zealand differ by ethnicity*. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you and your baby / pēpe receive. If you do want to take part now, but change your mind later, you can leave the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what will happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as whānau / family, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 8 pages long, including the Consent Form. Please make sure you have read and understood all the pages. You are welcome to an interpreter at any stage of the consent and study process if you wish.



## VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

Your choice to be a part of this study is completely voluntary. You are free to decline to participate, or to withdraw from the research, at any time without experiencing any disadvantage. Your decision to participate or not participate will not impact on the clinical decision making and care of you or your baby / pēpe.

## WHAT IS THE PURPOSE OF THE STUDY?

We want to gather information that will help us understand what factors may contribute to differing outcomes by ethnic group in babies born with serious heart conditions in New Zealand. By contributing your stories and opinions we hope to build a better picture of the journey whānau experience when they receive a diagnosis of critical heart disease. We hope to use this information to inform future health systems and processes to improve health equity outcomes for all.

## HOW IS THE STUDY DESIGNED?

Our study is designed to help us understand whānau experience of the healthcare system. We will collect information by interviewing parents / whānau / caregivers from different ethnic groups around Aotearoa / New Zealand, ensuring appropriate representation. Interviews will be in a private setting either face-to-face or by video-conference call according to your choice. Each interview is recorded and is expected to take approximately one hour. The question format is a semi-structured approach, meaning there is a broad set of questions designed to open-up conversation allowing exploration of key areas in more depth. We aim to interview at least 10-15 whānau / caregivers.

## WHO CAN TAKE PART IN THE STUDY?

Any parent(s) or caregiver(s) of a baby antenatally diagnosed with a life-threatening congenital cardiac condition.

## WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

Two one-hour interviews which will involve discussions around your experience of receiving the diagnosis of a heart problem in your baby. Questions will review the process of counselling, decision making and your experience with health care delivery and access for you and your baby. The first interview will be planned for at least 6 weeks after the baby's antenatal diagnosis, with the second interview offered after your decision has been made following the diagnosis or you have experienced a treatment pathway option. Interviews will either be by



video-conference call or face to face at a time and place of your choosing (including your own home). You can stop the interview at any time. After the interview is typed up you will be offered the transcript of the interview to check and edit if you so choose which could take an additional half an hour of your time.

### WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

The content of the interviews may bring up emotions which are distressing to you as they will discuss a very difficult time for you and your whānau, when you were informed that your baby has / had a heart defect. To try to minimise this risk of harm, care will be taken in the interview and you will only be asked to discuss content you are comfortable with. You can ask to stop the interview at any point. Additionally, information on where to seek psychological help will always be offered. We would not expect it to, however if the study evokes painful memories to the point of feeling like you might harm yourself or others the lead researcher will need to alert the appropriate agencies for everyone's safety.

### WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

A koha to the value of \$100 and kai will be offered, to show respect and appreciation of sharing your whānau's thoughts on your journey and to value your time (\$50 per interview). Another potential benefit may be in the process of reflection and discussion of your experiences with the researcher allowing your voice to be heard regarding your lived experiences.

### WHAT WILL HAPPEN TO MY INFORMATION?

During this study Dr Simone Watkins will record your interview and it will be transcribed into a word document which will be either sent by email or printed for you to cross check and edit if you wish.

#### Identifiable Information

Identifiable information is any data that could identify you or your baby (e.g. your name, date of birth, or address).

The following groups may have access to you or your baby's identifiable information:

- Dr Simone Watkins, the lead researcher
- Interview team (Dr Kim Ward, Dr Teuila Percival or Professor Sue Crengle)



### Security and Storage of Your Information.

Your identifiable information is removed from your data and held separately at the Liggins Institute during the study. After the study it is transferred to a secure archiving site and stored for at least 10 years and then destroyed. Your coded information will be entered into electronic case report forms and sent through a secure server to the sponsor. Coded study information will be kept by the sponsor in secure, cloud-based storage indefinitely. All storage will comply with local security guidelines. Your coded information will be available to the whole research team for potential analysis and review.

This research will ask you to fill in a form with you and your baby's basic information including ethnic group, geographic region, age range, highest level of education and gender. There is a small chance that due to the nature of the small group of individuals studied that the data, although de-identified, could potentially identify you.

Your de-identified data may be included in published study results including, but not limited to, peer-reviewed publications, clinical trial registry websites, scientific meetings, and regulatory submissions.

### Rights to Access Your Information.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

If you have any questions about the collection and use of information about you, you should ask Dr Simone Watkins.

### Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time, by informing Dr Simone Watkins.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you. Information collected up until your withdrawal from the study will continue to be used and included in the study.

## **WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?**

If you chose to withdraw please let the lead researcher, Dr Simone Watkins know of your intentions. You may still wish to be informed of the results of the study.

## **CAN I FIND OUT THE RESULTS OF THE STUDY?**

You can request to be emailed and/or printed and sent via mail a plain summary of the study results in your chosen language. The time frame for this will be within the year of the study completion which is expected to be 2024.



### WHO IS FUNDING THE STUDY?

A health research council grant was awarded to Dr Simone Watkins to financially support this study.

### WHO HAS APPROVED THE STUDY?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards.

### WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact either Professor Frank Bloomfield or Honorary Professor Tom Gentles and they can either provide assistance or facilitate you in receiving the appropriate support.

Professor Frank Bloomfield  
Director of the Liggins Institute  
Lead supervisor  
09 923 6107  
f.bloomfield@auckland.ac.nz

Honorary Professor Tom Gentles  
Service Clinical Director  
Paediatric and congenital cardiology  
Supervisor  
09 367 0000  
TomG@adhb.govt.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050  
Fax: 0800 2 SUPPORT (0800 2787 7678)  
Email: [advocacy@advocacy.org.nz](mailto:advocacy@advocacy.org.nz)  
Website: <https://www.advocacy.org.nz>



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For Māori support please contact:

Professor Sue Crengle  
Department of Preventive and Social Medicine  
The University of Otago  
03 4797202  
Sue.crengle@otago.ac.nz

For Pasifika support please contact :

Dr Teuila Percival  
Paediatrician and Pacific Researcher at Moana Research  
Teuila.Percival@middlemore.co.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHIC  
Email: hdec@health.govt.nz



## CONSENT FORM

**Study Title:** Why do outcomes of critical congenital heart disease in New Zealand differ by ethnicity?

Please let us know if you require an interpreter as this is available on request.

### Please tick to indicate you consent to the following

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I have read or have had read to me in my first language, and I understand the Participant Information Sheet.

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I have been given sufficient time to consider whether or not me and my baby will participate in this study.

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I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study.

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I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.

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I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting medical care for myself or my baby.

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I consent to the research staff collecting and processing me and my baby's information as outlined in the information sheet.

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If I decide to withdraw from the study, I agree that the information collected about me and my baby up to the point when I withdraw may continue to be processed.

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I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.

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I know who to contact if I have any questions about the study in general.

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I understand my responsibilities as a study participant.

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I wish to receive a summary of the results from the study. Yes  No



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**Declaration by participant:**

I hereby consent to me and my baby taking part in this study.

Participant's name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_