



## **Communicating Hypertrophic Cardiomyopathy (HCM) Genetic Test Results**

### **INFORMATION FOR PARTICIPANTS**

#### **Introduction**

You are invited to take part in a research study examining how we can best communicate genetic test results in hypertrophic cardiomyopathy (HCM). Genetic testing for genetic heart diseases like HCM has become increasingly complex and our method of explaining these results needs to evolve to meet these changing needs. Cardiac genetic counsellors coordinate the genetic testing process and they play a key role in ensuring the information you are receiving is clear and meaningful for you and your family. The objective of this study is to compare the effectiveness of an intervention aimed at improving the way we communicate genetic test result information with our current usual care. If you consent to the study, you will be randomly assigned to either the new communication intervention or to usual care.

Individuals with hypertrophic cardiomyopathy are eligible to participate in this study if they are the first in their family to have genetic testing. People aged 16 years or older are eligible to participate; however children younger than this are excluded.

The study is being conducted by Dr Jodie Ingles, Prof Christopher Semsarian, Ms Laura Yeates and Ms Charlotte Burns from the Molecular Cardiology Research Program, Centenary Institute and Royal Prince Alfred Hospital Sydney.

#### **Study Procedures**

If you agree to participate in this study, you will be asked to complete the participant consent form. You will then be randomly allocated to one of two groups, to receive your genetic test result. Two weeks after your genetic test result appointment, you will be asked to complete a survey (*either paper or online*), asking about your understanding of genetic testing for HCM. This survey will take between 10-20 minutes to complete.

**In addition, the researchers would like to phone you at one, three and six month intervals to follow up with you after you receive your genetic result. These phone calls will take approximately 10 minutes and will be conducted at a time that suits you.**

Researchers will have access to your medical record to obtain information relevant to this study. Information about you may also be sought from the *Australian Genetic Heart Disease Registry*, if you have enrolled ([www.heartregistry.org.au](http://www.heartregistry.org.au)). Confidentiality of the survey responses will be paramount. Your name will be replaced with a unique code and only Dr Jodie Ingles will have access to the true identity of respondents.

No additional genetic testing will be carried out as part of this study.

Information collected about you will be securely stored.

## **Benefits**

While we intend that this research study furthers medical knowledge and may improve management of genetic heart diseases in the future, it may not be of direct benefit to you.

## **Voluntary Participation**

Participation in this study is entirely voluntary. You do not have to take part in it. If you do take part, you can withdraw at any time without having to give a reason. Whatever your decision, please be assured that it will not affect your medical treatment or your relationship with the staff who are caring for you.

## **Confidentiality**

All of the information collected from you for the study will be treated confidentially, and only the researchers named above will have access to it. The study results may be presented at a conference or in a scientific publication, but individual participants will not be identifiable in such a presentation.

Any forms completed online, including the participant consent form and survey will be extremely secure to maintain participant privacy.

## **Further Information**

When you have read this information, one of the investigators is available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact:

### ***Dr Jodie Ingles***

Molecular Cardiology Research Program

Centenary Institute

Locked Bag No 6, Newtown NSW 2042

Ph. 02 9565 6293

Email. [j.ingles@centenary.org.au](mailto:j.ingles@centenary.org.au) Web. [www.heartregistry.org.au](http://www.heartregistry.org.au)

This information sheet is for you to keep.

## **Ethics Approval and Complaints**

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study should contact the Executive Officer on 02 9515 6766 and quote protocol number X16-0030.



# Communicating Hypertrophic Cardiomyopathy (HCM) Genetic Test Results

## PARTICIPANT CONSENT FORM

I, ..... [name]  
of .....[address]  
.....[email]

have read and understood the Information for Participants on the abovenamed research study and have discussed the study with .....

I have been made aware of the procedures involved in the study.

I understand that my participation in this study will allow the researchers to have access to my medical record, including information held by the Australian Genetic Heart Disease Registry (if I am enrolled), and I agree to this.

I freely choose to participate in this study and understand that I can withdraw at any time.

I also understand that the research study is strictly confidential.

I hereby agree to participate in this research study.

**NAME:** .....

**SIGNATURE:** .....

**DATE:** .....

**NAME OF WITNESS:** .....

**SIGNATURE OF WITNESS:** .....

Hello, this is (Insert Name) from the Centenary Institute, may I please speak to (Participant name)?

I am phoning (as we discussed back in (insert month of genetic result return) to follow up with you after you received your genetic result as part of our research into communicating genetic results. This is your (one month, three month, six month) follow up phone call. I was hoping to get some additional information from you regarding your gene result. Do you have 10 minutes or so to do this now- or I can arrange a more appropriate time?

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**SECTION 1: 3-generation pedigree documented – Have this documented prior to phone call. Confirm during phone call.**

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**SECTION 2**

**Who in the family have you told about the following: (List names/details):  
Your diagnosis of HCM?**

**About your genetic result?**

**Who in the family has had an echo/ecg/Cardiology review- Outcome?  
(Assess against guidelines)?**

**Who in the family has had genetic testing- Outcome?**

**Who in the family is awaiting an appointment- with whom?**

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**SECTION 3:**

Total number of first degree relatives informed of diagnosis =

Total number of first degree relatives informed of genetic test outcome=

Total number of first degree relatives who have had cardiology review=

Total number of first degree relatives who have had genetic review=

Total number of first degree relatives awaiting review=

Total number of first degree relatives with a positive clinical screen=

Total number of relatives with a negative clinical screen =

Total number of first degree relatives with a positive genetic result =

Total number of first degree relatives with a negative genetic result=

Total number of other relatives informed =