Garvan Institute of Medical Research

Kinghorn Centre for Clinical Genomics

Participant Information Sheet/Consent Form

Garvan Institute of Medical Research

Title	A qualitative study exploring experiences with return of genomic research results
Protocol Number	2020/ETH01938
Project Sponsor	Garvan Institute of Medical Research
Coordinating Principal Investigator	Mary-Anne Young, Garvan Institute of Medical Research
Principal/ Investigator(s)	Alison McEwen, University of Technology Sydney Angela Pearce, Garvan Institute of Medical Research Bronwyn Terrill, Garvan Institute of Medical Research Amanda Willis, Garvan Institute of Medical Research

Part 1 What does my participation involve?

1 What does my participation involve?

You are invited to take part in this research project, which is called "A qualitative study exploring experiences with return of genomic research results". It involves participating in an online focus group with approximately 4-5 other people. Participating in this research will require access to the internet and a device (for example, a computer) that you can use to join the online meeting via the Zoom platform. The focus group will be led by an experienced facilitator and will go for up to 60 minutes. We are also seeking people who would be willing to review the website that will be developed from the focus groups. This involves a one-one-one online interview up to 8 weeks after the focus group. This interview is optional.

This Participant Information Sheet 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. Please contact us to ask questions about anything that you don't understand or want to know more about.

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 consent by clicking a button in the consent section. By providing your consent 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 information as described
- Are over the age of 18 and have access to the internet and a smart device to join Zoom.

2 What is the purpose of this research?

The Kinghorn Centre for Clinical Genomics offers a service that helps to deliver genetic information to people who have participated in a genetic research study. This service is called My Research Results. As part of this service, we are developing a website that will contain information for people who have received genetic information. We are interested in your thoughts and ideas concerning the type of information you would expect to see on the My Research Results website.

3 What does participation in this research involve?

Your participation in this study will only start after you have consented to participate. You will be invited to participate in a focus group of 4-6 people. The focus group will run online through the Zoom platform and you may choose to participate with audio only or audio-video. The discussion will be around your experiences of receiving genetic information and the type of information that you did, or would have found helpful. The focus group will be led by an experienced facilitator and you will be asked for your opinion and thoughts throughout the session. There will be five focus groups run in total. We will use this information to build a website.

We are also seeking people who would be willing to review the website once it has been developed (about 8 weeks after the focus group). It would involve participating in a one-on-one online interview for about 45 minutes. The interview will also be conducted through the Zoom platform and you may choose to participate with audio only or audio-video. This part of the study is optional. If you do not wish to participate in an interview, you don't have to. You can choose just to participate in the focus group.

The research project, including analysing the results and writing about them, will be ongoing over a one year period. This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids everyone involved jumping to conclusions. There are no costs associated with participating in this research project. Participants will be reimbursed for their time: focus group participants will receive a $30 voucher and interview participants will receive a $25 voucher.

4 Other relevant information about the research project

This project involves researchers from The Kinghorn Centre for Clinical Genomics, Garvan Institute of Medical Research and Graduate School of Health, University of Technology Sydney.

The study will involve people from across Australia. We expect up to 25 people to be involved in the focus groups and will conduct up to 8 interviews.

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.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with the Garvan Institute of Medical Research or any medical researchers, genetic counsellors or other health care professionals.

It is up to you if you want to take part in the focus group and interview, or just the focus group.

6 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any direct benefits from this research. However, this study will help us to understand what information would be helpful for participants and will inform the content of the My Research Results website.

A reimbursement for your time will be provided. Participants in the focus group will receive a $30 voucher and participants who undertake an interview will receive a $25 voucher. Vouchers will be distributed at the conclusion of the group and/or interview.

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

There are limited risks with this research. However, some people may feel that talking about genetic research results is upsetting. If you feel this way during the focus group, the facilitator will be able to assist you. If required, you can take a break during the focus group. The facilitator may also talk to you about contacting your mental health care provider (if you have one), or they can offer a follow-up call

with you, or they can provide you with the details of a Genetic Counsellor who you can speak to free of charge.

8 What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. You can withdraw by either contacting the researcher prior to the focus group and/or interview, or by informing the facilitator during the group or interview. If you decide to leave the research project, the researchers will not collect additional information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results.

9 What happens when the research project ends?

The findings of this research will be used to inform the content of the My Research Results website. The results of the study may be written up as reports that are shared within the organisation or as other types of publications (such as presentations or journal articles) and shared with other researchers interested in this area. This process may take up to one year after we stop collecting information. If you would like to be sent a copy of any publications, please contact the researchers.

Part 2 How is the research project being conducted?

10 What will happen to information about me?

By consenting to the research online, you consent to the research team collecting and using information about you for the research project. Any information obtained in connection with this research project that could possibly 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. The personal information that the research team collect and use is information from the focus group and survey.

The discussion undertaken in the focus groups and interviews will be audio recorded and later transcribed. The audio recordings and the transcriptions will be stored in a password protected file that will only be accessible to the research team. Your personal details will be stored in an encrypted file accessible only to the contact researcher (Angela Pearce). Your personal details and the recordings and transcriptions will be stored separately. Pseudonyms will be used in place of names in any documentation. Data will be stored for a period of 5 years, after which it will be deleted from all servers and cloud-based applications. Any hard-copies will be shredded.

It is expected 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, for example, your name will not be used and only overall topics or themes that have been discussed will be presented.

11 Who is organising and funding the research?

This research has been initiated by: Mary-Anne Young, Head Kinghorn Centre for Clinical Genomics (Clinical), Garvan Institute of Medical Research.

This research is being conducted by the Garvan Institute of Medical Research and philanthropically funded by the Kinghorn Foundation.

12 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 St Vincent's Hospital. 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.

13 Complaints and compensation

If you experience any adverse effects or reaction as a result of participating in this research study, contact the study team who will assist you in obtaining appropriate medical treatment. You may also be able to seek compensation through the courts.

14 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, you can contact:

Research contact person

Name	Angela Pearce
Position	Psychosocial Research, Garvan Institute of Medical Research
Email	a.pearce@garvan.org.au

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 name	St. Vincent's Hospital HREC
Telephone	02 8382 4960
Email	SVHS.Research@SVHA.org.au