Participant Information Statement – *Healthcare Professionals*

Study Title	Exploring stakeholder perspectives and implementation considerations of genetic investigations for infertility
Short Title	Genetic testing for infertility
HREC Project Number:	105939
Principal Investigator	A/Prof Belinda McClaren

Introduction

Infertility is a global and increasing problem affecting approximately 1 in 6 couples. An example of this is primary ovarian insufficiency (POI) which is the leading cause of female infertility worldwide. POI is a complex, life-changing condition with significant physical and psychosocial aspects. In addition to the reproduction impact, POI can be associated with other health problems including heart disease, bone disease, and mental health conditions. Recent research has shown that genomic advancements show great promise in transforming health outcomes for women with POI and mainstreaming genetic investigations is becoming increasingly feasible. Mainstreaming in this context means genetic investigations being conducted outside of clinical genetic services, such as in medical specialities. An early genetic diagnosis is highly valued by patients, enabling personalised management options, appropriate counselling and advice, predictions of related health risks and access to early intervention.

This research study seeks to provide evidence for better care for people who are having genetic investigations for the cause of their infertility. The increasing availability and affordability of genetic testing means that genetic investigations are likely to be considered when infertility is being cared for. Those providing such testing will not always be genetic experts and it is not known how non-genetic medical and health professionals will approach genetic testing, and what their needs are to support offering testing to patients.

What is the purpose of this research?

This research study aims to explore the perspectives of healthcare professionals on mainstreaming genetic investigations for POI and infertility. In a separate study we will also be asking consumers their views on the value of and their experience with genetic testing for infertility. We aim to identify and address barriers to implementation and discuss the clinical utility of genetic testing for POI.

Who is running this research project?

This project is being conducted by researchers at the Murdoch Children's Research Institute and the University of Melbourne.

What does participation in this research involve?

You will be invited to participate in a qualitative interview, to provide insights into your experience providing genetic testing and counselling to patients with fertility issues. The interview may take 30 minutes and flexibility will be provided to accommodate a time and interview length suitable to you. Interviews can be done online/in person, depending on your preference. Before starting the interview, we will ask you to provide your consent to participate.

Do I have to take part in this research project?

Participation in the interview is voluntary, and you may stop completing the interview at any time. During the interview you may request to stop the recording if you'd like to make comments off-tape and you may also request that the researcher take only notes in response to a question. If you decide to withdraw from the research project, you should be aware that data collected up to the timepoint you notify us of your withdrawal will form part of the research project results.

Your relationship with your employer and the study team will not be affected by your decision about whether to participate in the research. There are no costs involved in participating in this research, nor will you be paid.

What are the possible risks and benefits of taking part?

Your participation is expected to pose minimal risk and psychological discomfort from the interview is not expected. Your contribution to the research will require your time, which may be an inconvenience for you.

What will happen to information about me?

Interviews will be recorded using a digital recorder (over the phone) or via a video conferencing platform (if held online). Audio files will only be accessed for the purpose of transcription or verification of information by a member of the study team. An external transcription service approved by MCRI may be used.

Potentially identifying information you give in the interview, such as names of colleagues will be removed at the point of transcription and replaced with text such as: [name of colleague]. Your interview transcript will be assigned an identifier such as HCP01. The name of hospital you are employed by will be replaced with Hospital A or Hospital B. A key to link transcript identifiers to participant contact details will be kept separate from the interview transcripts and restricted to access only by the principal researcher and select project team members, under supervision of the principal researcher, for the purpose of managing participant contact and data analysis.

Audio files and transcripts will be stored on MCRI secure cloud-based network in folders accessible only to the research team. Data will be stored for seven years after completion of the research activities. At the end of the data storage period, data will be disposed of in a secure manner, as appropriate at the time of destruction.

In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. Please inform the research team member named at the end of this document if you would like to access your information.

What happens when the research project ends?

Research results will be disseminated via conference presentations and in peer reviewed scientific journals. If you are interested, we will provide you a copy of the study results when this study finishes.

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 the Royal Children's Hospital. This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007) updated 2018. This statement has been developed to protect the interests of people who agree to participate in human research studies.

Further information and who to contact

If you would like further information concerning this project you can contact:

Name	A/Prof Belinda McClaren
Position	Principal Investigator
Email	belinda.mcclaren@mcri.edu.au

If you have any complaints about any aspect of the project and the way it is conducted or any questions about being a research participant in general, you may contact:

Reviewing HREC name	Royal Children's Hospital Human Research Ethics Committee
HREC Executive Officer	Director
Telephone	(03) 9345 5044
Email	rch.ethics@rch.org.au