THE UNIVERSITY OF SYDNEY
SYDNEY MEDICAL SCHOOL – NORTHERN
Master of Genetic Counselling

GARVAN INSTITUTE
Breakthrough Medical Research

Principal Supervisor: A/Prof Marcel Dinger
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Title: Exploration of Australian stakeholder views regarding the impact of Next Generation Sequencing on genetic counselling

PARTICIPANT INFORMATION STATEMENT

(1) What is this study about?

You are invited to take part in a research study exploring the opinions of representative stakeholders working within the field of genetics, on the impact of next generation sequencing (NGS) on genetic counselling.

You have been invited to participate in this study because you have been identified as a representative stakeholder working within the genetics/health-related community.

This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part in the research. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

Participation in this research study is voluntary. So it's up to you whether you wish to take part or not.

By giving your consent to take part in this study you are telling us that you:
- ✓ Understand what you have read
- ✓ Agree to take part in the research study as outlined below
- ✓ Agree to the use of your personal information as described.

You will be given a copy of this Participant Information Statement to keep.

(2) Who is running the study?

The study is being carried out by the following researchers:

- A/Prof Marcel Dinger, Head of Clinical Genomics and Genome Informatics, Kinghorn Centre for Clinical Genomics, Garvan Institute for Medical Research.
- Bronwyn Terrill, Coordinator for Public and Professional Education, Kinghorn Centre for Clinical Genomics, Garvan Institute for Medical Research.
- A/Prof Kris Barlow-Stewart, Director, Master of Genetic Counselling Genetic Medicine, Northern Clinical School.
- Kirsten Boggs, Master of Genetic Counselling student, University of Sydney Medical School, Northern Clinical School.

Kirsten Boggs is conducting this study as the basis for the degree of Masters of Genetic Counselling at The University of Sydney. This will take place under the supervision of A/Prof Marcel Dinger, Head of Clinical Genomics and Genome Informatics, Kinghorn Centre for Clinical Genomics.

(3) What will the study involve for me?

Along with this Information Sheet, you have been sent a consent form. If you are interested in participating, please print out the attached consent form, sign it and scan and email the signed copy to Kirsten Boggs (Master of Genetic Counselling student researcher) at kbog3229@uni.sydney.edu.au Kirsten Boggs will then contact you to arrange an interview time convenient to you. Your interview will be audio recorded. The interview questions will ask your opinions on the potential impact of NGS on genetic counselling. Some questions will be based around the five hypothetical scenarios, and will involve discussing the issues associated with those situations.

(4) How much of my time will the study take?

The study will take approximately 45 minutes of your time. This includes 15 minutes of reading time, and a telephone interview, which will take approximately 30 minutes.

(5) Who can take part in the study?

The population of interest for this study is defined as representative stakeholders who work within the genetics community. This includes genetic counsellors, clinical geneticists, oncologists, pathologists, researchers, educators, ethicists and other interested stakeholders.

(6) Do I have to be in the study? Can I withdraw from the study once I've started?

Being in this study is completely voluntary and you do not have to take part. Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney, the Garvan Institute of Medical Research or the Kinghorn Centre for Clinical Genomics.

If you decide to take part in the study and then change your mind later, you are free to withdraw at any time. You can do this by contacting the research team.

You are free to stop the interview at any time. Unless you say that you want us to keep them, any recordings will be erased and the information you have provided will not be included in the study results. You may also refuse to answer any questions that you do not wish to answer during the interview. The information provided in the interviews will be audio-recorded, transcribed and then de-identified. It will not be possible to withdraw your responses after this as they will be anonymous and we will not be able to tell which one is yours.

(7) Are there any risks or costs associated with being in the study?

Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study.

(8) Are there any benefits associated with being in the study?

We cannot guarantee or promise that you will receive any direct benefits from being in the study.

(9) What will happen to information about me that is collected during the study?

Demographic information will be collected such as age, sex, years of experience, public/private workplace context and profession. You will not be asked about your role or the program you are delivering, and no data will be collected about your genetics service. The professional information will be sorted into broad categories so as to limit identifiability. Audio recordings will be taken and transcribed verbatim, then de-identified and audio tapes will be destroyed. Transcripts will be used for analysis and interpretation only. Any personal information collected will be kept confidential and will be stored until the study is complete. Data will be stored on a secure hard drive, held in a locked filing cabinet in A/Prof Marcel Dinger's office at the Kinghorn Centre for Clinical Genomics Level 6, which can only be accessed via swipe card for authorised and approved personnel. Once the study is complete the materials will be transferred and held in a locked filing cabinet in the office of A/Prof Kristine Barlow-Stewart, Level 7 of the Kolling Institute, Royal North Shore Hospital. The data will be destroyed after 7 years.

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

Your information will be stored securely and your identity/information will be kept strictly confidential, except as required by law. Study findings may be published in peer reviewed publications and presented at scientific conferences. Although every effort will be made to protect your identity, there is a risk that you might be identifiable in publications due to the nature of the study and/or the results. The research team listed, are the only ones who will have access to your information.

(10) Can I tell other people about the study?

Yes, you are welcome to tell other people about the study.

(11) What if I would like further information about the study?

When you have read this information, Bronwyn Terrill at Kinghorn Centre for Clinical Genomics will be available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage during the study, please feel free to contact them on 02 9355 5842 or email b.terrill@garvan.org.au.

(12) Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. This feedback will be in the form of a one to two page lay summary. You will receive this feedback via email after the study is finished.

(13) What if I have a complaint or any concerns about the study?

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney (2014/909). As part of this process, we have agreed to carry out the study according to the *National Statement on Ethical Conduct in Human Research (2007).* This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:

- **Telephone:** +61 2 8627 8176
- **Email:** ro.humanethics@sydney.edu.au
- **Fax:** +61 2 8627 8177 (Facsimile)

This information sheet is for you to keep