



CONSENT FORM

Study Title: GenCOUNSEL – Activity 3.2A

Contacts:

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What is GenCOUNSEL?

GenCOUNSEL is a Canada-wide project to look at the challenges of bringing new genomic sequencing technologies to Canadians. There are many different parts to this large study. This consent form talks about just one part.

Why are we doing this part of the study?

The genome is the name for all our genetic material – this is what controls how our bodies work. Genomic testing is the name for a group of new tests that sequence large amounts, or all, of a person's genome at once. The genome is the set of instructions that guide our bodies' functioning. You or your family has recently been offered one of these tests and your doctor has probably explained a bit about it.

We have designed a new way to guide families through learning about genomic sequencing and helping them to make the decision whether or not to have the testing. We are now studying how well it is working and what we can do to make it better for all Canadians. We will follow about 100 families as they learn about sequencing and make their decision. By asking people how they are learning and how they are feeling about the process, we hope to make this new system work well for most Canadians. For example, we are making information available in six different languages on the internet and on paper.

What happens in the study?

If you choose to participate in the study, we will provide you with your own personal link to an online tool called DECIDE. It is designed to give you information and help your decision making. It will work on a computer, smart phone or tablet. We want to know how good it is at giving information and helping you choose about testing. There are some questions that are part of DECIDE that look at what you have learned and how you feel about the decision. Don't forget, we are not testing you, we are measuring how well DECIDE works! You never have to answer any questions you don't want to.

Next you will get to choose if you would like to see a genetic counsellor. This can be in-person, on the telephone, or by a video link like Skype. Some people may choose to go straight to testing without talking to a counsellor. Seeing the genetic counsellor may allow you to ask any questions that weren't answered by DECIDE and can help you if you are still having uncertainty about the testing.

About three months after you make your decision about testing, we'll contact you again. The purpose this time is to see how you feel about your decision now that some time has passed. By this time, people who choose testing will have got their results. Again, this is a short online questionnaire.

Finally, we will have audio-taped interviews with about 15 people. We will randomly ask people if they would like to be interviewed. We hope that this will give people a chance to tell us about the experience in as much detail as they want. In this way we will learn different things about the testing experience. If you would particularly like an interview, please let us know and we can add you to the 15 people.

Study Results

The main study findings will be used to improve DECIDE and the process of guiding people through the genomic sequencing testing process. Results may be published in academic journal articles.

Risks of Participating

We do not think there is anything in this study that could harm you. But please let one of the study staff know if you have any concerns or anxieties.

Benefits of Participating

There are no direct benefits to you for participating. You may get some satisfaction by knowing that you are helping to shape part of the healthcare system.

Confidentiality

If you take part in the interviews, which are audio-recorded, the recordings will be transcribed (typed out) using code numbers instead of names. The recordings and transcripts will be kept on a secure and password protected computer system.

Consent forms and questionnaire data are on a secure hospital system using a tool called REDCap to organize the information. If the questionnaire data are downloaded to analyze, we will use code numbers to identify them and will keep the files in a secure computer system, protected by a password.

Throughout the study, your confidentiality will be respected. Information that discloses your identity will not be released without your consent unless required by law. Any paper documents will be identified only by code number and kept in a locked filing cabinet. Participants will not be identified by name in any reports of the completed study. All data will only be used by the study team during the study itself and will be destroyed 5 years after the end of this part of the study. This includes consent forms, questionnaire data, audio files and transcriptions.

Contact information about the study

Please feel free to contact Dr. Elliott, the principal investigator, Shelin Adam, the study's genetic counsellor, or Valerie Chu, research assistant, at the contact information on the first page. If we are not available, please leave a message and we'll get back to you as soon as possible.

Contact for complaints

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the UBC Office of Research Ethics at 604-822-8598 or if long distance e-mail RSIL@ors.ubc.ca or call toll free 1-877-822-8598. Please reference the study number (H18-03275) when contacting the Complaint Line so the staff can better assist you.

Gen-COUNSEL (Activity 3.2A)
Consent

Taking part in this study is entirely up to you. You have the right to refuse to participate in this study. If you decide to allow us to contact us now, you may choose to pull out of the study at any time without giving a reason and without any negative impact on your health care or relationship with anyone in the Department of Medical Genetics, the University of British Columbia. To pull out of the study, please contact a member of the study team on page 1 of this consent form.

Your signature below indicates that you have received a copy of this consent form for your own records.

Your signature indicates that you consent to participate in the study.

Signature Printed First & Last Name Date

Your child's name

Interpreter, if used:

Signature Printed First & Last Name

Please send this signed page back to us by email: gencounsel@bcchr.ca or fax: 604-875-2376