3. Consent Form

INFORMED CONSENT FORM FOR PARTICIPATION IN A RESEARCH STUDY

Study Title	The Genetics Navigator: Evaluating a Digital Virtual Care Tool for Genomics Health Services
Study Doctors	Dr. Yvonne Bombard, St Michaels Hospital, Li Ka Shing Knowledge Institute. XXX-XXX-XXXX x XXXXX Dr. Robin Hayeems, Child Health Evaluative Sciences, The Hospital for Sick Children. XXX-XXX-XXXX x XXXXX Dr. [*insert name of local investigator], [insert name of clinic], [insert contact info of local investigator]*
Funder	Canadian Institute of Health Research
Contact Number:	XXX-XXX-XXXX x XXXXX

INTRODUCTION

You are being asked to take part in a clinical trial (a type of study that involves research). You are being asked to consider taking part in this research study because you are a patient who is within the circle of care of *insert recruiting practitioner* at *insert recruiting hospital*. For this study, we want to find out how helpful an online application called the Genetics Navigator is for patients who are offered genetic testing. This consent form provides you with information to help you make an informed choice about participating. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

Please take your time in making your decision. You may find it helpful to discuss it with your friends, family, or your physician.

Taking part in this study is voluntary. Deciding not to take part or deciding to leave the study later will not affect current or future health care.

IS THERE A CONFLICT OF INTEREST?

Neither you nor the members of the study team will realize any financial gain directly from this study. Dr. Bombard, Dr. Hayeems, and the other research team members have no conflict of interest to declare.

WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?

For this study we have created an online tool called the Genetics Navigator that helps patients through their journey of learning about and receiving genetic testing and genetic test results. Genetic testing is increasingly being used for patient care and there are a variety of genetic tests that can provide answers for a person's health condition. Although the demand for genetic testing is increasing, there are not enough genetics healthcare professionals to meet the demand of delivering genetic services to patients. As a result, our research team has developed an online tool called the Genetics Navigator to fill in this gap. In this study, we want to find out how helpful the Genetics Navigator is for patients who are offered genetic testing. The Genetics Navigator is meant to provide information about genetic testing, help patients make decisions about genetic testing, and provide genetic test results and recommendations for patients. The

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study is interested in comparing the effectiveness of the Genetics Navigator compared to traditional medical appointments with genetic counsellors and medical geneticists.

If you agree to participate, you will be actively involved in the study for 6 months.

WHY IS THIS STUDY BEING DONE?
The main purpose of this study is to understand how effective our online program is in helping patients who are undergoing genetic testing.

WHAT OTHER CHOICES ARE THERE?
You do not have to take part in this study in order to receive standard treatment or care.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
It is anticipated that about 150 people will take part in this study from research sites located in Ontario.

WHAT WILL HAPPEN DURING THE STUDY?
If you decide to participate in the study, you will be asked to verbally consent to participation in the study. A copy of this consent form will be given to you.

Once you consent to participate in the study, we will ask you a series of questions about your health history, and some questions about your current feelings, emotions, and expectations about having genetic testing.

Participating in this study will not affect your care. Regardless of whether or not you participate in this study, you will still receive the same standard of care from your genetics clinic at *insert recruiting hospital.* Standard of care means that you will meet with a genetics clinician about your health and to discuss the possibility of having genetic testing. If you decide to have genetic testing, the standard of care also means that you will meet with your genetics clinician to discuss your genetic test results and to determine the next steps with regards to your care.

After you answer these questions, you will be "randomized" to participate in one of two study groups, described below. Randomization means that you are put into a group by chance (like flipping a coin). There is no way to predict which group you will be assigned to. You will have an equal chance of being placed in either group. Neither you, the study staff, nor the study doctors can choose which group you will be in.

If you are in group one you will use our online application prior to speaking with a genetics clinician. The application will teach you about genetic testing and will help you decide if genetic testing is something you would like to receive. Group one participants will also use the online application to prepare for learning their results and to view their results, either before or after speaking with their genetics clinician about their results (when you see your results will be decided by your clinician). If you are in group one, you will have the same interactions with your genetic care team as you would if you did not participate in this study. Using the online application will not replace any part of your normal care.

If you are in group two you will speak with your genetics clinician to learn about and decide if genetic testing is something you would like to receive. Group two participants will also speak with their genetic clinician to prepare for learning their results and to learn about their results.

Both groups will have genetic testing performed if they choose to receive it, and both groups will receive results from genetic testing. The genetic testing is being performed as part of your usual care and is not being offered by the study team. No matter the group you are assigned to, there is a chance that no results

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will be found. Below is an explanation of what you will be asked to do depending on which group you are randomized to participate in:

Group One (Using the Genetics Navigator and speaking with a genetics clinician about your results)

- If you are selected to participate in group one, two weeks prior to your scheduled appointment with your genetics clinician, we will provide you with a link to view the Genetics Navigator digital application. The application will contain videos explaining genetic testing and the possible results you could learn. It will also ask you to share your personal and family health history. You will receive a user name to login to the application from the study team.

- The application may also ask you to upload photos of yourself (e.g. face, hands, feet) to help your doctor with clinical decisions. This is optional.

- After you view the application and answer the questions you will be asked to indicate whether you would like to receive genetic testing. Your indication at this point will not be your final decision; you will have a follow up discussion with your genetics clinician to come to a final decision about having genetic testing.

- The application will ask a set of questions about your feelings about receiving genetic results and what is important to you when thinking about receiving these types of results.

- We will ask you to use the application prior to your appointment with your genetics clinician. It will take you approximately 45 minutes to view and complete the Genetics Navigator online and complete the follow-up questions.

- During your meeting with your genetics clinician, your clinician will have access to the information you entered into the application and they may use this to help them during your appointment.

- After speaking with your genetics clinician, we will email you a link to a survey with questions about what you learned about genetic results, your feelings about receiving these results, your satisfaction with your decision and your general feelings.

- Once your genetic test results are ready, you will be contacted by your genetics clinic to inform you that your results are ready and to schedule an appointment.

- At your genetics clinician's discretion, you will either receive your genetic test results first on the Genetics Navigator platform and then meet with your genetics clinician to discuss your results, or you will receive your genetic test results first at your meeting with your genetics clinician and will then be able to go onto the Genetics Navigator platform to view your results. After you review your results, you will be asked to answer some follow-up survey questions about your feelings about your results, your satisfaction with your decision to receive genetic testing, and your general feelings.

- Using the Genetics Navigator to view your results and answering the follow-up question will take 20-30 mins to complete.

- Throughout the process, you will have the opportunity to discuss your genetic test results with your genetics clinician and ask any questions you may have.

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- After completing this final set of follow-up survey questions your participation in the study will be over.

Group Two (Speaking with your genetics clinician only about your results):

If you are selected to participate in group two, you will go through the same steps as group one with a couple of differences because you will not be using the Genetics Navigator. These differences include:

- You will not use the Genetics Navigator platform at any point in the study. Instead, you will receive standard care from your genetics clinician. This will include learning about genetic testing, deciding to receive genetic testing, and receiving your results from your genetics clinician.

- If you are in group two, all the other steps are the same as outlined above in group one.

- After each meeting with your genetics clinician, you will complete follow-up survey questions.

Some participants from both groups one and two (approximately 40 in total) will be asked to complete a conversational interview after they have completed all of their study visits. This interview will be conducted over the phone with our study staff. We will ask you about your thoughts and experiences using the Genetics Navigator platform (if applicable), learning about your genetic test results, and how you have used this information in your health decisions. This interview will take about an hour and can be scheduled at a date and time of your choosing. This visit will be audio-recorded and transcribed.

We will ask you not to use your name, or the name of any relatives during the interview. Any names and identifiers will be deleted during the transcription process, which is called de-identification. Transcription is taking the words and dialogue on the audiotape and writing or typing it word for word. Transcription will be performed by Rev.com, an external encrypted and secure transcription service.

TIMEPOINT	ACTIONS	
Consent and Baseline	• Baseline questions • Randomization into Group One or Group Two	
	GROUP 1 (65 participants)	**GROUP 2** (65 participants)
	Will use the Genetics Navigator platform and speak with their genetics clinician to learn about and receive genetic testing and results.	Will speak with their genetics clinician only to learn about and receive genetic testing and results.
Timepoint 1: Prior to Clinician Meeting	• Use Genetics Navigator platform on computer, tablet or smart phone to learn about genetic testing • Answer follow-up survey questions	• No meeting or actions at this time point
Timepoint 2: Clinician Meeting	• Meet with your genetics clinician • Review any items that may need clarification	• Standard of care appointment with genetics clinician to learn about and make a decision to receive genetic testing

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	• Confirm eligibility and decision to receive genetic testing • Answer follow-up survey questions	• Answer follow-up survey questions
Timepoint 3: Receive Results	• Receive test results from genetics clinician at clinican appointment* • Discuss any need for follow-up and referrals • Answer follow-up survey questions • Receive email notification from Genetics Navigator on computer, tablet or smart phone to review results and management plan* • Answer follow-up survey questions **Order may vary at your genetics clinician's discretion*	• Standard of care appointment with genetics clinician to receive your genetic test results • Review results in detail • Discuss any need for follow-up and referrals Answer follow-up survey questions
Timepoint 4 (Optional): After receiving results	• Phone call with study team • Conversational interview (not for all participants, but only for those who are selected to participate - 40 participants in total)	• Phone call with study team • Conversational interview (not for all participants, but only for those who are selected to participate - 40 participants in total)
	ACTIVE PARTICIPATION ENDS	ACTIVE PARTICIPATION ENDS

WHAT ELSE DO I NEED TO KNOW ABOUT THE STUDY?
You do not need to participate in this study to receive genetic testing. You can still receive standard of care genetic testing from your genetics clinician at *insert recruiting hospital* even if you do not participate in the study. Any risks associated with receiving genetic testing will be addressed by your genetics clinician, as is standard of care.

If you participate in this study, we would like your permission to access your medical records at *insert recruiting hospital*. We will only collect the information we need for the study, which will include your medical history, any treatments received, any genetic test you've had or may have (if applicable), any diagnoses made based on your genetic testing, and the amount of time your visits with genetics clinicians took. We will use this information only for study purposes. We will not be adding or changing any information in your medical record at any hospital or clinic. All data collected for research purposes will be kept separate from any of your medical records and will be stored in a secure research record at St. Michael's Hospital.

Your genetics clinician at insert recruiting hospital is also part of the study team, and will also be

informed about your participation in this study. If you are in group one and use the Genetics Navigator platform, your genetics clinician will have access to the information that you enter into the platform.

WHAT KINDS OF QUESTIONS WILL I BE ASKED?

Examples of the types of questions you will be asked in the study include:

> "*How strongly do you agree with this statement: I know what health resources are available on the internet."* or
>
> *"Does your health limit you in any of the activities you might do during a typical day?"* or
>
> "*How strongly do you agree with this statement: I can explain what the condition means to people in my family who may need to know.*" or
>
> "*How strongly do you agree with this statement*: *This decision is easy for me to make*."

Examples of the types of questions you will be asked if you take part in the phone interview about receiving genetic testing include:

> *"What information was most helpful in learning about and deciding to have genetic testing? What information did you think was unnecessary? What information most influenced your decision?"* or
>
> *"After using the Genetics Navigator platform, did you feel motivated or ready to receive genetic testing?"*

WHAT SHOULD I KNOW ABOUT ANSWERING STUDY QUESTIONS ONLINE?

For those selected to participate in group one, the Genetics Navigator platform you use is online, using the Internet. This will require the use of a computer or tablet or smartphone with access to the Internet. If you do not have access to a computer or the Internet, you can contact the study research coordinator and we will arrange to get you access to a computer and/or the Internet at St. Michael's Hospital to participate in the study. To access the Genetics Navigator platform you will need a link to the correct Internet address where you will be able to create your own personal account. We will provide you with a link to the correct Internet address over the phone or via video conferencing. We use Google Analytics to gather information about what type of device study participants use to access the Genetics Navigator platform, such as a computer, phone, or tablet. Through Google Analytics, we will also collect information on how often study participants use the platform, how long they spend on each page, how often they log in and out of the platform, and where in the platform they log out. Google Analytics gathers information on IP address, which could be used to identify you. However, Google Analytics does not share this information with any user, they only use if for internal purposes. Through Google Analytics, the research team will not be able to identify you as the data received by the research team from Google Analytics does not include information such as your name, email, your phone number, or IP address. The data we analyze from Google Analytics will only be analyzed at the overall group level. This information is important to us for improving the user experience and determining platform effectiveness.

WHAT WILL YOU DO WITH THE RESULTS OF MY GENETIC TESTING?

If you are in group one you will be able to view your results in the Genetics Navigator platform and with your genetics clinician; the order may vary at your genetics clinician's discretion. If you are in group two, you will receive your results only from your genetics clinician as is standard of care.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

If you choose to participate in this study, you will be expected to:

- Allow the study team to access your medical records at *insert recruiting hospital*.

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- Use an online platform to help you decide with your genetics clinician about receiving genetic testing (group one only)
- Complete questionnaires at the time-points listed above with members of the study staff, over the phone or online. Questionnaires will include questions about your demographics, your decision making, moods, feelings, and medical history. You may decline to answer any questions you wish.
- Participate in a semi-structured interview with a member of the study team, over the phone. Only 40 participants will be contacted for this.

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?
The total time period for this study will be about 6 months. Depending on what group you are in there will be 2-4 study visits. The visits will be via computer program, conference call, or over the phone. Study sessions are described in detail above.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?
You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. If you choose to withdraw from the study, you are encouraged to contact the study staff to inform them of your decision. Any data that has been collected by the study team and is stored at St. Michael's Hospital or in the Genetics Navigator platform (if randomized to group one) up until the point of your withdrawal will remain as part of the study data unless you request for it to be removed. Participation in this study, and the details of any decisions you make about your participation, will in no way affect any aspect of the care you or your family are receiving from St. Michael's Hospital, *insert recruiting hospital*, any hospital, health care facility, or any medical staff.

CAN PARTICIPATION IN THIS STUDY END EARLY?
Participation will end if you choose to withdraw. If you are to become ill again and feel that will impact your ability to participate, you may choose to withdraw yourself.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THE STUDY?
It is possible that you may experience distress from participating in this study. If you do experience any emotional distress or discomfort, we will help you get a referral to a psychologist or psychiatrist. In addition, you are always free to refuse to answer any particular questions at any time if you feel uncomfortable. If you are experiencing acute distress, we will refer you to your nearest emergency room.

If you are in group one and experience distress when using the Genetics Navigator platform, the study genetic counsellor will discuss this distress with you and will provide you with support. The study genetic counsellor will also inform your genetics clinician of your distress, and your genetics clinician will provide continued support. It is important to note that the study genetic counsellor is only available during business hours and will only be available to discuss your distress during this time. If you are experience acute distress and are unable to contact the study genetics counsellor or your genetics clinician, you may contact your local emergency department for support.

If you require any additional counseling sessions or mental health services as a result of participating in this study that are not covered by OHIP or private insurance, these costs will not be reimbursed by the study. Any distress that may arise due to any clinical genetic test results that you may receive will be managed by your clinical genetics team, as is standard of care.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?
You may not benefit from participating in this study. Ultimately, this research will allow doctors and

genetic counsellors to assess the effectiveness of the Genetics Navigator platform to help with the genetic testing process.

IS MY PARTICIPATION VOLUNTARY?
Yes, your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. You may leave the study at any time without affecting your or your family's care. You may refuse to answer any question(s) you do not want to answer, or not answer a question by saying "pass" or selecting "skip" when answering questions.

WHAT IF I AM INJURED IN THIS STUDY?
If you become ill, injured or harmed as a result of taking part in this study, you will receive care. The reasonable costs of such care will be covered for any injury, illness or harm that is directly a result of being in this study. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions of their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.

HOW WILL PARTICIPANT HEALTH INFORMATION BE KEPT CONFIDENTIAL?
If you decide to participate in this study, the study doctors and study staff will only collect the information they need for this study.

Records identifying you at St. Michael's Hospital will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) medical/clinical study records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

- The research ethics board who oversees the ethical conduct of this study in Ontario
- This institution and affiliated sites, to oversee the conduct of research at this location

The following organizations may/will also receive study data:
- St. Michael's Hospital

Representatives of Clinical Trials Ontario, a not-for-profit organization, may see study data that is sent to the research ethics board for this study. Your name, address, or other information that may directly identify you will not be used. The records received by these organizations may contain your *participant code.*

Studies involving humans sometimes collect information on race and ethnicity as well as other characteristics of individuals because these characteristics may influence how people respond to different interventions. Providing information on your race or ethnic origin is voluntary.

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be used in analyses and will be published and presented to the scientific community at meetings and in journals.

For group one participants, your information in the Genetics Navigator platform will be stored on a server hosted by MedStack, a secure PHIPAA-compliant platform for digital healthcare. The MedStack server is located in Canada and adheres to the privacy and security standards required by St. Michael's Hospital.

Using the platform will require you to provide personally identifiable information as well as person health information. This information in the platform may include your patient name, date of birth, contact information (email), personal and family health history, photographs of hands, feet and face, and genetic test results. It is not mandatory to provide your personal and family health information (including photos) in the Genetics Navigator platform. MedStack and the study team will keep your information protected and will not share this information with any outside individual or organization. This data will only be able to be accessible by the study team and your clinical genetics team, and will be removed from the server after the study has completed data collection. Accidental public disclosure may occur such as unintended data breaches by hacking or other activities outside of the procedures authorized by the study. In such a case, your data may be misused or used for unauthorized purposes. If there is breach will notify you and well take any necessary steps to protect information where possible. Any of the data this is collected or stored by the Genetics Navigator platform will not be added to your patient record at (insert hospital).

For all participants, your answers to questionnaires will be entered into an online data collection software called REDCap. The data collected will be stored on a server that resides at St. Michael's Hospital. This data will be removed from the server after the study has completed data collection.

Information will not be directly disclosed to insurance companies or employers.

Finally, we will ask for your email in order to communicate with you during the course of the study. We will only use email for communication purposes, we will not ask for and share any data via email. Please note that the security of email messages is not guaranteed. Messages may be forged, forwarded, kept indefinitely, or seen by others using the internet. Do not use email to discuss information you think is sensitive. Do not use email in an emergency since email may be delayed. If you do not wish to use email for communication, we will use phone and/or mail to communicate with you.

HOW WILL THE RESEARCH DATA BE STORED?
All study data, files, and material will be kept at St. Michael's Hospital, in a secure area. All computer files will be kept on servers at St Michael's Hospital and will conform to all privacy and confidentiality laws.

All of the study data (responses to questionnaires in REDCap) will have any identifiable information removed. Each participant and their answers (data) will be assigned a specific code and only the principal investigator will have the "code key" which can link the codes back to the data. The code key will be kept on a secure server at St. Michael's Hospital and will only be accessible to the principal investigator.

Information that we transfer from our study locations to our study offices at St. Michael's Hospital will be entered manually onto the secure server at St. Michael's Hospital by our study staff.

The information that is collected for the study will be kept in a locked and secure area by the study doctor for 10 years. Only the study team or the people or groups listed below will be allowed to look at your records. Study data will be stored on the secure servers at St. Michael's Hospital. We will retain all study data for 10 years after the completion of the study.

The audio recordings that are a part of the conversational interview portion of this study will be downloaded to servers at St Michael's Hospital. All conversational interviews will be transcribed for analysis purposes. Transcription is taking the words and dialogue on the audiotape and writing or typing it word for word. We will ask you not to use your name, the names of any relatives, or any other identifying information during the interview. No identifiable information will be sent to the external company, we will only identify your interview by your study number. Once the transcription is complete and the content is verified, we will destroy any audio files. The de-identified transcripts will be uploaded to an encrypted

online software called Dedoose for analysis. The transcript uploaded to Dedoose will not contain any identified information about you. Once the analysis is complete, your file will be removed from the Dedoose software. Dedoose software servers are located in the United States.

If you have any concerns about this, or have any questions, please contact the St. Michael's Hospital Privacy Office at 416-864-6060 (or by email at privacy@smh.ca).

WILL THE RESEARCH DATA BE SHARED WITH OTHER RESEARCHERS?

General research results (such as number of participants in the study, combined preferences for receiving genetic testing, average age of all the participants, etc.) may be shared with other researchers to support their research work. This data will be shared directly by the study Principal Investigator. Any of this type of data that we share will be de-identified and will not contain your personal identifiable information and cannot be linked back to you. We would provide this information to investigators who are studying similar topics to this study, such as genetic conditions or the usefulness of genetic testing. Data might be shared with researchers who want to learn about the usefulness of genetic testing, or about how people feel about learning genetic test results, or other types of similar research. Any investigators wishing to use this data would need to seek approval from the Research Ethics Board at their own institute, would be bound to protect the data by a data sharing agreement and would not be allowed to share the data with other researchers.

WILL INFORMATION ABOUT THIS STUDY BE AVAILABLE ONLINE?
A description of this clinical trial will be available on https://www.clinicaltrials.gov/. This website will not include information that can identify you. You can search this website at any time. When research results from the study are published, publications will be available online.

If you participate in the conversational interview part of the study, direct quotes from your responses may be used in reports or publications, but the quotes will not be attributed to you or contain any information that could be used to identify you. These quotes will be found in publications about the study results and most of these publications can be accessed online.

WHAT ARE THE COSTS TO PARTICIPANTS?
You will not be charged for your participation in this study. You will not be charged for genetic counselling that is directly related to this study. We will reimburse you for out-of-pocket expenses incurred as a result of being in this study (for example meals, babysitters, parking and getting to and from St. Michael's Hospital for this study, if applicable). If you withdraw from the study, we will pay you for your expenses for taking part in the study up until that point.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?
You will not be paid for taking part in this study.

It is possible that the research conducted using your study data may eventually lead to the development of new diagnostic tests, new drugs or devices, or other commercial products. There are no plans to provide payment to you if this happens.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?
You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. To receive results from the study, you can contact the research team, or indicate below that you wish to be contacted

by the study team about the end of study results presentation.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

You will be given a copy of this signed and dated consent form prior to participating in this study.

WILL I LEARN THE RESULTS OF THE STUDY?
We will hold an end of study results presentation, and will contact participants about this presentation once it is available. If you would like to be contacted about this end of study results presentation, or other study updates related to this study, please indicate this below. If you would not like us to contact you with study updates, we will ensure that your name is not kept for future contact.

WILL I BE CONTACTED AFTER I HAVE COMPLETED THE STUDY?
We would like your permission to re-contact you after the study has completed. We will not share your contact information with anyone. You would only be contacted by members of the study team via email or phone. You may be re-contacted and invited to participate in follow-up research to get your feedback on this consent process, the Genetics Navigator platform, or other studies related to genetic testing. We might contact you to invite you to participate in follow-up research to this study, such as research about how you feel about your genetic test results in the long term. We may contact you to invite you to participate in other studies related to the topic of genetics and genetic testing. We will provide you with additional information about new research studies and provide you with a separate consent form when we contact you. You can decline to take part in any future research when you are approached and are not obliged to participate if you have agreed to be re-contacted. If you agree to be re-contacted you can remove yourself from this list at any time by contacting the principal investigator or the study coordinator. If you do not wish to be re-contacted, you can still take part in this study. Your contact information will be kept at St. Michael's Hospital on a computer located on servers at St. Michael's Hospital that conform to all privacy and confidentiality laws. Only study staff will have access to your contact information. We will keep your re-contact information for 10 years, after which time we will no longer contact you without your permission. If you do not wish to be contacted in the future, tell the person consenting you and they will ensure your name is not kept for future contact.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

Study Contact
If you have questions about taking part in this study, or if you suffer a research-related injury, you can talk to the study investigator, or the investigator who is in charge of the study at this institution. That person is:

- Dr. Yvonne Bombard, PhD, Principal Investigator XXX-XXX-XXXX
- Dr. Robin Hayeems, PhD, Principal Investigator XXX-XXX-XXXX
- Marc Clausen, Research Coordinator XXX-XXX-XXXX
- *Inset name and phone of Principal Investigator at recruiting site*

Research Ethics Board Contact
If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. That person is:

Unity Health Toronto Research Ethics Board Chair XXX-XXX-XXXX ext. xxxx

VERBAL INFORMED CONSENT FOR
The Genetics Navigator: Evaluating a Digital Virtual Care Tool for Genomics Health Services

For Consenting Study Staff
Instructions for consenting study staff: Read out consenting statement on page 20 of the consent form. Complete checklist below.

VERBAL CONSENT CHECKLIST

Did the participant receive a copy of the consent form before or during the telephone conversation?
Yes ☐ No ☐ If yes, was the form sent by: Fax ☐ Email ☐

Name of Participant:

		CLEAR		RE-EXPLAINED
		YES	NO	YES
Voluntary				
1.	Does you agree to participation in the research study?	☐	☐	☐
2.	Once you have verbally consented, do you have to stay in the research study until the end?	☐	☐	☐
3.	If you decide not to consent to the study, will the way health care providers feel about you change in any way?	☐	☐	☐
About the Research Study				
4.	What is the purpose of the study? Do you understand the study procedures and what your participation in the study will involve?	☐	☐	☐
Risk and Benefits				
5.	What are the benefits of being in the study?	☐	☐	☐
6.	What are the risks of being in the study?	☐	☐	☐
Confidentiality				
7.	Will your study files be kept confidential?	☐	☐	☐
Time Required				
8.	How long will you be required to participate in this study?	☐	☐	☐
Reimbursement				
9.	Will you be paid for taking part in this study?	☐	☐	☐
Questions				
10.	If you have specific questions about this study, who should you ask?	☐	☐	☐
11.	If you have questions about being involved in a research study in general, who should you ask?	☐	☐	☐
Medical Records				
12.	Will your medical records be accessed and for what reason?	☐	☐	☐
Sharing Results and Data				
13.	Do you give permission for your research results/study data to be shared with other researchers?	☐	☐	
Permission for contact about study results				
14.	Do you agree to being re-contacted by study staff about study results?	☐	☐	
Permission for re-contact about future studies				
15.	Has re-contact been explained? Do you agree to being re-contacted by study staff?	☐	☐	

CONSENT STATEMENT I have explained to the patient the nature and purpose, the potential benefits, and possible risks associated with the participant's participation in this research study. I have answered all questions that have been raised by the participant.

_____	_____	_____
Printed name of Person Conducting Consent	Signature of Person Conducting Consent	Date and Time (24h clock)