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Genetics Adviser: evaluating a digital decision support tool for genetic results  
Consent Form- Incidental Genomics Participants (SMH)

## INFORMED CONSENT FORM FOR PARTICIPATION IN A RESEARCH STUDY

<b>Study Title</b>	Genetics Adviser: evaluating a digital decision support tool for genetic results
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<b>Funder</b>	Canadian Institute of Health Research
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### 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 were a participant in the Incidental Genomics study that took place at St. Michael's Hospital. For this study we are looking to enroll people for whom a new type of genetic test called "genomic sequencing" might discover a gene(s) related to their cancer. The purpose of the study is to understand if an online computer program can help people learn about genetic testing and select what type of results they would like to receive from 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 and the other research team members have no conflict of interest to declare.

### WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?

Genetic testing is evolving and there is a new type of genetic test called "genomic sequencing".

- **Traditionally**, if a person has a disease, such as colorectal cancer, he or she may be referred to a genetics clinic to have a genetic test to learn if they have a genetic variation (or change in their DNA) that increases their risk to develop this type of cancer. This type of test only looks at specific genetic variations known to be linked with a specific type of cancer.

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- **Genomic sequencing** is another type of genetic test that looks more broadly at all genetic variations that a person has, rather than looking at specific variation as explained above.

Some (but not all) of the genetic changes or variations found in genomic sequencing may be linked to higher risks of diseases. When a person gets genomic sequencing they can learn about risks for a disease affecting them, such as colorectal cancer. But they may also have the option to learn extra genetic information about risks for diseases other than the original disease being investigated. This extra information is often referred to as “secondary” or “incidental results”. These incidental results can tell if a person has, or is at risk for, a rare disease, like Alzheimer’s disease, or common diseases, like heart disease, or even other cancers. It is also important to know that even if a person gets genomic sequencing, there is a chance that no changes related to disease risks will be found.

For this study we have created a decision aid to help people decide which type of incidental findings they would like to learn (if any). There are decision aids for many diseases and medical conditions and they are commonly used in the medical field to assist patients. The decision aid we have designed for incidental findings gives a person information about incidental findings, information about the different categories of incidental findings and provides information about the potential impact of this information. The decision aid then asks a set of questions to help a person decide what type of incidental findings (if any) they would like to receive. The decision aid will also help people get prepared for having their incidental results returned to them and will also let them see a summary of their results once they are available.

For this study we are interested in comparing the effectiveness of our decision aid against traditional genetic counseling. We anticipate that no more than 140 people in total will be enrolled in the study.

You will be actively involved in the study for 6 months. As a part of this study you will be receiving (or have already received) genomic sequencing and will be receiving actual incidental results.

#### **WHY IS THIS STUDY BEING DONE?**

The main purpose of this study is to understand how effective our decision aid is in helping patients select what type of incidental result they would like to receive from genomic sequencing.

#### **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 140 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 the 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 medical history and genetic testing, some questions about your current feelings, emotions and expectations about having genomic sequencing.

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

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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 decision aid and speak with genetic counselor to learn about and select which incidental results you would like to learn. Group one participants will also use the decision aid to prepare for learning their results and to receive a preview of their results before they speak with genetic counselor about their results. If you are in group two you will speak with a genetic counselor to learn about and select which incidental results you would like to receive. Group two participants will also speak with a genetic counselor to prepare for learning their results and to learn about their results. Both groups will have genomic sequencing performed and both groups will receive results from genomic sequencing. Because you participated in a study with us previously where you received genomic sequencing results for your cancer, you will only receive incidental results and will not receive any further results related to your cancer. There is a chance that no results 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 a decision aid and speaking with a genetic counselor about results)**

- If you participate in group one, we will verbally provide you with a link to view the decision aid online. The decision aid will contain videos explaining genetic testing and the possible results you could learn. You will receive a user name and password for the decision aid from the study team verbally once you have been randomized. At the end of decision aid you will be asked to choose which results you would be interested in receiving
- After you are done using the decision aid we will ask you some survey questions related to using the decision aid.
- After you complete the decision aid and answer the survey questions you will speak with a genetic counsellor over the phone or via computer conferencing
- The genetic counselor will speak to you about your decision on what to learn from the genetic testing. The types of questions they will ask will be related to your understanding of the topic and your preferences for learning about genetic test results. During your genetic counselling session, you will also have an opportunity to ask any questions you may have after using the decision aid.
- Your session with your genetic counsellor will be audio recorded so that we can verify the session for consistency.
- After speaking with the genetic counsellor, they will ask you some survey questions about what you learned about genetic results, your feelings about receiving these results, your satisfaction with your decision and your general feelings.
- It will take you approximately 1 hour to view and complete the decision aid online, complete the follow-up questions and to complete the counseling session.
- During this consent process we will ask for your permission to re-analyze your exome sequence from the Incidental Genomics that you previously participated in. If you do not wish to use this sequence then we will take a saliva sample. From your saliva sample we will extract a sample of your DNA and this sample will be used for genomic sequencing. If you need to provide a saliva sample, we will send you a saliva sample kit to your

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home. The kit will contain instructions on how to prepare your sample and how to return the sample to the study team.

- After you have selected which results you would like to receive, we will re-analyze your exome sequence or arrange to have your DNA sample sequenced. An exome sequence is a type of genetic test that looks at most of the changes found in your DNA. Exome sequencing was the type of genetic test you had a part of the Incidental Genomics study. It is estimated that it will take 4-5 months to get your sequencing results, however it may take up to 6 months.
- Two weeks after you have selected which results you would like to receive, we will ask you to complete online survey questions about what you learned about incidental findings, your feelings about receiving these findings, your satisfaction with your decision and your general feelings. We will send you an email with a link the survey.
- Two months after your first meeting where you used the decision aid we will send you a message to log back into the decision aid to prepare you to learn your results. The decision aid will give you information about the possible results you could receive, ask you about your feelings about receiving results and provide resources to help prepare for your results.
- After using the decision aid we will ask you to answer some follow-up survey questions about what you learned about incidental findings, your feelings about receiving these findings, your satisfaction with your decision and your general feelings. We will send you an email with a link to the survey which we will ask you to fill out after you have used the decision aid.
- Using the decision aid to prepare for your results and answering follow up questions will take 20 min to complete.
- Once we have your results a genetic counsellor will contact you to set up a phone or computer conference call meeting to discuss your results.
- One week before your scheduled meeting with the genetic counselor you will be sent an email with instructions to log into the decision aid. In the decision aid you will be able to review a summary of your results. The summary will give you a brief description of any findings, the possible implications for your health and any recommended medical actions. After using the decision aid to preview your results we will ask you to answer some follow-up survey questions about what you learned about incidental findings, your feelings about receiving these findings, your satisfaction with your decision and your general feelings. We will send you an email with a link to the survey which we will ask you to fill out after you have used the decision aid.
- Using the decision aid for your results and answering the follow-up question will take 20 mins to complete.
- In the meeting with the genetic counselor one week later, the genetic counselor will review your result with you in detail and will discuss any further plans or referrals that are recommended. During this meeting, the genetic counselor will also share with you a detailed report on your results and after the meeting will mail or email you a copy of this detailed report.

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- If for any reason during the analysis processes we find results requiring urgent, immediate action, prior to the 4-5 month time for return of results, these results will be returned as soon as possible; you will not have to wait 4-5 months.
- At the end of the meeting where we discuss the results from your genomic sequencing, we will ask you to complete a questionnaire about your feelings about receiving your incidental results and your health actions. The meeting about your results and completing this questionnaire will take you approximately 1 hour to complete.
- After completing this this final set of follow-up survey questions your participation in the study will be over.

**Group Two (Speaking with a genetic counselor only about results):**

If you are 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 decision aid. These differences are:

- You will not use the decision aid at any point in the study. Instead, you will speak with a genetic counselor over the phone or by computer conferencing to learn about and select genomics sequencing results.
- The two-month time point to prepare for receiving results will be conducted by a genetic counselor over the phone or by computer conferencing.
- You will not receive a preview of your results, rather you will learn about your results the first time when you have the final meeting with the genetic counselor.
- If you are in group two all the other steps are the same as outlined above in group one.
- After each meeting with the genetic counselor you will complete follow up survey questions.

Some participants from both groups 1 and 2 (approximately 40 in total) will be asked to complete a conversational interview after they have completed all the study visits. This interview will be conducted over the phone or via computer conferencing with our study staff. We will ask you about your thoughts and experiences using the decision aid, learning about your 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 also audio record all of your genetic counseling sessions and a subset of these sessions will be transcribed. This is being done so we can do quality checks on the session and, as part of our research, we will look at what types of questions patients have about genomic sequencing and incidental results.

We will ask you not to use your name, or the name of any relatives during both the genetic counseling sessions and the conversational 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 Flying Fingers, an external transcription service that has a signed service provider and confidentiality agreement with our team.

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TIME		
	GROUP 1 (70 participants)	GROUP 2 (70 participants)
	Will use the decision aid and speak with a genetic counselor to select and learn about genomics testing results.	Will speak with a genetic counselor only to select and learn about genomics testing results.
Meeting 1: First meeting	<ul style="list-style-type: none"> <li>• Complete baseline questions and randomization with study coordinator over the phone or computer conferencing</li> <li>• Use decision aid on computer, tablet or smart phone</li> <li>• Select what type of results to learn</li> <li>• Answer follow-up survey questions</li> <li>• Speak with study GC</li> <li>• Review any items that may need clarification</li> <li>• Review and confirm results selection</li> <li>• Answer follow-up survey questions</li> </ul>	<ul style="list-style-type: none"> <li>• Complete baseline questions and randomization with study coordinator over the phone or computer conferencing</li> <li>• Phone call or computer conference call with study GC</li> <li>• Select what type of results to learn</li> <li>• Answer follow-up survey questions</li> </ul>
	<ul style="list-style-type: none"> <li>• Sample sent for sequencing</li> </ul>	<ul style="list-style-type: none"> <li>• Sample sent for sequencing</li> </ul>
Meeting 2: two weeks after first meeting	<ul style="list-style-type: none"> <li>• Complete online follow up survey</li> </ul>	<ul style="list-style-type: none"> <li>• Complete online follow up survey</li> </ul>
Meeting 3: 2 months after sample sent for sequencing.	<ul style="list-style-type: none"> <li>• Use decision aid on computer, tablet or smart phone</li> <li>• Prepare for your results</li> <li>• Answer follow-up survey questions</li> </ul>	<ul style="list-style-type: none"> <li>• Phone call or computer conference call with study GC</li> <li>• Prepare for your results</li> <li>• Answer follow-up survey questions</li> </ul>
Meeting 4: 1 week before final meeting with study GC (when results are ready – approx. 5 month from first meeting)	<ul style="list-style-type: none"> <li>• Use decision aid on computer, tablet or smart phone</li> <li>• Preview results</li> <li>• Answer follow-up survey questions</li> </ul>	No meeting or actions at this time point.
Meeting 5: When results are ready – approx. 5 months from first meeting)	<ul style="list-style-type: none"> <li>• Phone call or computer conference call with study GC</li> <li>• Review genomic results in detail</li> </ul>	<ul style="list-style-type: none"> <li>• Phone call or computer conference call with study GC</li> <li>• Review genomic results in detail</li> </ul>

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	<ul style="list-style-type: none"> <li>• Discuss any need for follow-up and referrals</li> <li>• Answer follow-up survey questions</li> </ul>	<ul style="list-style-type: none"> <li>• Discuss any need for follow-up and referrals</li> <li>• Answer follow-up survey questions</li> </ul>
Meeting 6: After last meeting with study GC	<ul style="list-style-type: none"> <li>• Phone call with study team</li> <li>• Conversational interview (not for all participants, but only for those who are selected to participate - 40 participants in total)</li> </ul>	<ul style="list-style-type: none"> <li>• Phone call with study team</li> <li>• Conversational interview (not for all participants, but only for those who are selected to participate - 40 participants in total)</li> </ul>
	ACTIVE PARTICIPATION ENDS	ACTIVE PARTICIPATION ENDS

### WHAT ELSE DO I NEED TO KNOW ABOUT THE STUDY?

This study is not the only way to have genomic sequencing. Genomic sequencing is available outside of the study for a cost. If you are interested in this outside of the study, you can talk to your physician.

If you participate in this study, we would like your permission to access your medical records at the genetics clinic where you were being seen for your cancer diagnosis. We will only collect the information we need for the study, which will include past cancer diagnoses, any past treatments for cancer, past genetic testing type and results. We will use this information to confirm your cancer history, any treatments received, and your genetic testing history.

In this study we will inform your clinicians at the genetics clinic where you were being seen for your cancer diagnosis about your participation in this study. Results from the study will not be placed in your medical file. All reports that are produced from this study will be clearly labeled as a research result. Because these are labeled as research results, this might mean that you will need follow-up genetic testing to confirm some results.

Also, as a part of this study we will audio record and analyse your sessions with our study genetic counsellor. We will use this information to study what sorts of questions and comments people have when learning about incidental results and genomic sequencing.

Finally, we would also like to collect the name and contact information of one of your family members to whom you would like your genomic sequencing results returned to. In the event that you pass away before receiving sequencing results and a life-threatening, actionable result is found that might impact other family members, this result would be shared with the family member you indicated. It is in their best interest to learn about it so that they may make decisions that could help them or other family members take actions to reduce their risk of developing a disease. Only life-threatening, medically actionable information would be shared; no other genetic information would be shared. You will have the opportunity to ask this family member their permission to share their name contact information with the study team before you provide this information to the study team. You also do not have to provide the contact information of a family member to share this information with.

In the event that I die before I receive the results from my genomic sequence I do **not** give my permission for the study staff to share any life threatening genetic results with anyone.

In the event that I die before I receive the results from my genomic sequence I **do** give my permission for the study staff to share any life threatening genetic results only with

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the person I have provided.

\_\_\_\_\_  
Participant's Name

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

### **Use of Your Exome sequence**

If you previously had genomic sequencing with one of our studies, we would like to use this sequence for analysis in this study. If you do not agree to use your exome sequence for this study, then a saliva sample will be taken after your initial consent session. From your saliva a sample of DNA will be extracted. Your saliva sample will be sent to a laboratory at The Hospital for Sick Children's Centre for Applied Genomics (TCAG), where your DNA will be extracted and then it will be sequenced. DNA and saliva samples will not be stored or used for any other research purposes. DNA and saliva samples will be destroyed once sequencing has been done.

I do **not** give my permission for my exome sequence from the Incidental genomics to be used in this study for analysis .

I **do** give my permission for my exome sequence from the Incidental genomics to be in this study for analysis .

\_\_\_\_\_  
Participant's Name

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

### **How will samples and my genetic sequence be identified?**

To protect your identity, the information that will be on your sample and or genetic sequence will be limited to your study ID number. Despite protections being in place, there is a risk of unintentional release of information. Due to technological advances in genetics, there may be a risk that the genetic information in the samples could be linked back to you.

### **Can I withdraw these samples?**

If you no longer want your samples or sequence to be used in this research, you should tell the study coordinator, who will ensure the samples and sequence are destroyed.

If sequencing has already been done on your sample it will not be possible to withdraw your sample, since it will have been destroyed after sequencing.

### **WHAT KIND OF RESULTS COULD I LEARN?**

If you chose to learn about medically actionable results, you might learn that you have a higher than average risk for certain types of heart problems like irregular heartbeats that can be life-threatening. You also might learn about how you react to some medications.

Other incidental findings that you might learn could be related to risk for common diseases like Type 1 diabetes. Or, you might learn about your risk for rare genetic disorders, like muscular dystrophy, or some types of progressive deafness. You might learn about risk for brain-diseases like Alzheimer's Disease. You might learn if you are a carrier for genetic diseases, like cystic fibrosis, that probably will not affect you, but that you might be able to pass on to your children. These are just a few examples of the types of results that you might learn. You will be able to choose what types of incidental findings you would like to learn, if any.



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Lots of information can be found from genomic sequencing. Some genomic sequencing results are known to be linked to risk for diseases. The meaning of some other results is not known. We will only give you results that are **known** to be linked to diseases.

Finally, there is always a chance that even if you have genomic sequencing, no results known to be linked to diseases will be found.

### **WHAT KINDS OF QUESTIONS WILL I BE ASKED?**

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

*“How important is it for you to learn about your risk for common diseases that you can reduce with a healthy diet & exercise?”* or

*“How important is it for you to learn that you may get an untreatable brain disease so you can tell or prepare your family?”* or

*“How strongly do you agree with this statement: I feel sure about what to choose.”* 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 decision making include:

*“What information was most helpful in your own decision-making? What information did you think was unnecessary? What information most influenced your decision?”*

*“After using the decision aid, did you feel motivated or ready to make a decision? Did you feel you had the ability/skill to make this type of decision?”*

### **WHAT SHOULD I KNOW ABOUT ANSWERING STUDY QUESTIONS ONLINE?**

For those selected to participate in group 1, the decision aid 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. To access the decision aid you will need a link to the correct Internet address along with a unique login code. We will provide you with a link to the correct Internet address along with your unique login code over the phone or via video conferencing. None of the questions in the decision aid contain any personal information about you. The decision aid will gather data about what type of computing device you use to access the program (personal computer, phone or tablet). This information will not be able to identify you and it will not gather any other information about you from your computer session.

Also, if you are in study group 1 that is using the decision aid you will also be asked to answer some follow up questions online. The decision aid will automatically link you to these study questions and you will be able to log into this survey using the same unique login code you use for the decision aid.

### **WHAT WILL YOU DO WITH THE RESULTS OF MY GENOMIC SEQUENCING?**

If you are in Group One you will be able to view your results in the decision aid and the study genetic counselor will discuss your results with you. If you are in Group Two, you will receive your results from the study genetic counselor only.

You will be referred to a specialist for any results that we find that may impact your health. The study genetic counsellor and medical geneticist will develop referrals and consult notes, which they will give to the genetics clinic where you were being seen for your cancer diagnosis, who

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will facilitate referrals to specialists. The type of specialist will depend on the nature of the disease risk found in your genomic sequence. For example, you may be referred to a cardiologist if results suggest that you are at increased risk for a heart condition. It is possible that we will find multiple results that will require referrals to multiple specialists. You also may receive some results that may not have a direct impact on your health, but may be important for you to be aware of. These types of results you will be able to share with your general practitioner. If you do not have a general practitioner, we will help locate one.

After the genetic counsellor gives your results to you in person or over the phone, we will mail you a full copy of the results which will indicate any referrals that have been made for you. You will also have the option of receiving your results by email via secure file transfer. You can change your mind about which incidental results you would like to receive at any time in the study up until the time when we return results to you. At the time when we return results, you may decide not to learn some of the information about those incidental results that you had previously decided to learn about. However, it is possible that we may learn some information about your health that we will still return to you because it will be very important for your health. This will only be information that we learn that is critical to your health. If you wish to add to the list of incidental results you would like to learn, you may do so up until the time you get your results back, but adding results will delay the return of your results as we will need to go back and reanalyze your information. As well, if you decide not to learn about certain categories of results, you will not be able to learn those results after the study is over. This is because we will have not analyzed these results originally and will not be analyzing them again after the study is over.

It is possible that scientists will learn more in the future about the meaning of your genomic sequencing results. At this time, we do not plan to contact you in the future to discuss any new knowledge. Also, genomic sequencing can detect changes in your DNA known to be related with a certain disease or condition. However, genome sequencing may also reveal DNA changes that are not known to be related with a particular disease or condition. These are known as “variants of uncertain significance”. Over time, as we learn more about DNA changes and variants of uncertain significance, we may find out that they are disease-causing or harmless. In this study where you are receiving incidental results, we will only look for and return results to you that are known to increase risk for a disease or condition. For incidental results we will not look for or return any “variants of uncertain significance”.

This research may tell us about the way you are related to your family. It may tell us that you or your family members are not related. If such information is found, we will not tell you or anyone else.

Finally, it is important to note that if you receive a positive result, it does not mean that you are guaranteed to develop that disease. The results you receive are estimates of risk and if you are found to have a genetic variant you may or may not develop that disease or condition in your lifetime. Also, if you are found not to have a variant for a disease or condition you may still develop the disease. It could be that our test did not detect the variant or that something else may cause you to develop the disease.

### **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 the genetics clinic where you were being seen for your cancer diagnosis.

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- Allow the study team to access a DNA sample stored at Mount Sinai Hospital or North York General Hospital, or provide a saliva sample.
- Use an online Decision Aid and make a decision about the type of incidental findings you would like to receive from genomic sequencing, if any (group one only)
- Allow the study team to communicate your genomic sequencing results and information about your participation with your clinicians at the genetics clinic where you were being seen for your cancer diagnosis.
- 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 and feelings, 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. Not all participants will be contacted for this, about 40 will be in total.

**HOW LONG WILL PARTICIPANTS BE IN THE STUDY?**

The total time period for this study will 6 months. Depending on what group you are in you there will be either 4 or 6 study visits. The visits will be via computer program, conference calling software or 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 genetic counselor or study staff to inform them of your decision. 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, the genetics clinic where you were being seen for your cancer diagnosis, any hospital, health care facility or any medical staff

If you leave the study and your DNA or saliva sample has not yet been used for sequencing, your DNA or saliva sample will be withdrawn and destroyed. If your DNA has already been used for sequencing, any leftover sample will have been destroyed. If you leave the study after sequencing is complete, your raw genomic sequence data will be destroyed, unless it has already been uploaded for data sharing, after which it will not be possible to remove it from the database, however you will be able to remove the sequencing data from the study itself. The results of the analysis of your sequence data, and any other information recorded before you withdrew (e.g. questionnaire responses) will still be used by the researchers for the purposes of the study, but no information will be collected after you withdraw. Any data that we do hold onto will be kept confidentially and will not contain your name or any other identifying information.

**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?**

There are some possible risks to learning information from genomic sequencing and incidental findings. It is possible that you may experience distress from participating in this study or from learning about your genomic sequencing results. 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 experience distress related to study results (positive or negative) the study genetic counsellor will discuss this distress with you. If necessary, you will be provided online and phone contact information for patient support groups. If you seem overwhelmed, the genetic counsellor will ask if you would like a referral to a mental health specialist for more long-term support.

In these cases, the study genetic counsellor will work with the genetic counsellor at the clinic that referred you to this study to get you a referral to a psychologist or psychiatrist. The genetic counsellors will work with you through this process to ensure that you follow through with the referral and seek further care. We may also recommend you seek a referral through your family doctor / general practitioner. If the genetic counsellor feels that you need immediate mental health service, they will refer you to the emergency department at St. Michael's Hospital or your closest emergency room. In this case, the genetic counsellor will work with you to ensure you receive follow up care.

Since distress may occur at any time during the study, please contact the study team if at any time you experience any distress as a result of the study. We will put you in touch with the study genetic counsellor, who will ensure that the appropriate care is delivered.

The cost of counseling sessions or mental health services that are a result of participating in this study and are not covered by OHIP or private insurance will not be reimbursed by the study.

If you choose to share your results with your family members or others, it may affect how they feel about you, or how you feel about them. For these reasons, you and your family may wish to seek further counseling. In some cases you may want to see a mental health professional.

There is a chance that your genetic information may be used against you or your family members. This is a form of discrimination. Canada recently passed a legislation (Bill S-201) that makes genetic discrimination illegal. For instance, it is illegal for insurance companies, employers or other parties to use genetic testing results against you, or to force you to reveal the result of a genetic test. However, we cannot fully guarantee you that no one will ever use your research test results against you.

Your participation in this study is confidential; however there is a small chance that your genetic data (results from genomic sequencing) could identify you or your family members. This is because each person's genomic make-up is unique, similar to a fingerprint. Because your family's genetic make-up is very similar to yours this means that your sequencing data could potentially identify them. We will do everything to ensure that your identity is protected; but because of the uniqueness of your genetic data we cannot guarantee confidentiality for you or your family members.

### **WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?**

You may not benefit from participating in this study. With your sequencing information you may learn new information about your risks for various diseases. You may or may not find this information helpful. Ultimately, this research will allow doctors and genetic counsellors to assess the effectiveness of a decision aid for selecting which results to learn from genetic testing.

### **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 you 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.

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Consent Form- Incidental Genomics Participants (SMH)**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 and/or your samples:

- St. Michael's Hospital
- The Centre for Applied Genomics at SickKids Hospital (who provides sequencing)
- Dr. Lerner-Ellis' laboratory at Mount Sinai Hospital (who analyses the sequencing data)
- The genomic analysis system used by Dr. Lerner-Ellis' laboratory

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.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated. It is important to note that the genomic sequencing data we gather from you is inherently identifiable because it contains your unique genetic make-up. In order to protect your genomic sequencing data, we will de-identify the information, meaning we will remove any identifiable information, such as name and date of birth, from the data set. However, because the data contains your unique genetic make-up, the data cannot ever be fully de-identified.

For group 1 one participant, your de-identified answers in the decision aid will be stored on a server that is located in the United States. This data will be removed from the server after the study has completed data collection. By signing this consent form, you agree to the use and

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transfer of your de-identified study data, outside of Canada where data protection laws differ from those of Canada. Once information is transferred outside Canada, it is subject to the data privacy laws of that country where it is stored. There are laws that allow government authorities access to personal information under certain circumstances. In the USA, for example, lawful disclosure of personal information to the government is permitted for certain national security purposes under the USA PATRIOT Act.

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?**

There are two different types of data in this study that will be stored differently: Raw genomic sequencing data, and general study data.

Raw data from genomic sequencing has the most potential to identify you or your family. This data will be stored at St. Michael's Hospital in our study files and at the lab at Mount Sinai Hospital that will analyze your sequencing data. To analyze your genetic information we use a web based analysis software. To use this software we will have to upload your sequence information to their program. This will be the only information we will upload, and we will not upload any other information about you such as your name, date of birth or anything else that could identify you. Since we will only upload is actually only part of your genetic sequence (called an exome) and we will not provide the software with any other information about you, no one will be able to identify you using the data uploaded to the software. The servers that the software uses may be located outside of Canada, but we will ensure that software we use will store the data in way that is compliant with Canadian privacy protection standards. Only study staff will have access to the data uploaded on the software and software vendor will not own this data and once we are done analyzing your information it will be removed from the software's server.

It is also possible that this data will be uploaded to an external database that helps scientists learn more about how genetics are linked to disease (see section below, *Will the research data be shared with other researchers?*). If this data is uploaded, it will not contain any of your identifiable information. This data will not be included with the general study data.

Your genomic data will be analyzed to look for changes that might impact your health. The results of this analysis will be a list of all of the changes (variants) found in your DNA that you requested to learn. You cannot be identified from this type of data (the changes found). This data will be added to the general study data.

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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 (questionnaires, results of sequencing analysis) 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, including contact information and sequencing 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 this study will be downloaded to servers at St Michael's Hospital. All conversational interviews will be transcribed and a subset of the genetic counselling sessions will also be transcribed for analysis purposes, which may include your session. Transcription is taking the words and dialogue on the audiotape and writing or typing it word for word. During transcription all names and identifiers will be deleted; this is called de-identifying. This transcription will be conducted by an external service. No identifiable information will be sent to the external company, we will only identify your interview by your study number. There will be a confidentially agreement with the outside transcription company. Once the transcription is complete and the content is verified, we will destroy any audio files. The deidentified 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.

The decision aid used in the study will ask you questions but does not ask for or store any identifying information. There are parts of the decision aid that you are able to input your own answers. We ask that you not enter any information that could identify you or family members in these sections.

DNA samples will be destroyed after sequencing and will not be stored.

If you participate in this study, information about your genetic variants found as a result of this research project will not be stored in your hospital file at the genetics clinic where you were being seen for your cancer diagnosis] unless you ask the hospital to add this information to your file. If you do ask that this information is added to your file, some institutions involved in this study share the patient information stored on its computers with other hospitals and health care providers in Ontario so they can access the information if it is needed for your clinical care. This information would the type of genetic testing you had, the results of your genetic test and any referrals that were made. 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](mailto:privacy@smh.ca)).

## **WILL THE RESEARCH DATA BE SHARED WITH OTHER RESEARCHERS?**

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All data related to the study, including genomic sequencing results and your clinical data, may be shared with other scientific investigators.

DNA and saliva samples will not be shared or used for any other research purposes.

1. **Raw genomic sequence data and phenotype data (information about physical and clinical characteristics such as cancer diagnosis)** may be shared with other researchers in two ways:
  - a. **Directly by the study Principal Investigator:** Any researchers wishing the Principal Investigator to share this data for research purposes must seek approval from the Research Ethics Board at their own institution for their research study, would be bound to protect the data by a data sharing agreement and would not be allowed to share the data with other researchers.
  - b. **Uploaded to a genetics databases for data sharing.** Your sequencing data and phenotype data may be put in a controlled-access database. This means that only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your genomic data and health information will not be labeled with your name or other information that could be used to identify you. Researchers approved to access information in the database will agree not to attempt to identify you. The databases we would share genetic sequencing and phenotype data with are restricted to researchers investigating cancer and/ or genetic variations.

Sharing this data directly with other researchers and with the genetics data sharing databases would be done so other researchers can use this information to better understand genetic variations related to any disease (including cancer) and what genetic changes might cause disease. When we share this data, all direct identifiers (e.g. your name, date of birth) will be removed and only a code-key will be used to identify it. It is important for you to know that genetic data is unique and therefore non-confidential. There is a chance that you or your family may be identified by your sequence data. There is also the risk of accidental release of your information (other parties other than the intended researchers seeing your data). Although this risk is small, it can never be completely eliminated.

**You may participate in the study without agreeing for us to share your genetic sequence and phenotype data. Please indicate your choice below.**

I do **not** give my permission for my genomic sequence and phenotype information to be shared with other researchers and uploaded to genetics data sharing databases.

I give permission for my genomic sequence and phenotype information to be shared with other researchers and uploaded to genetics data sharing databases.

---

Participant's Name

---

Signature

---

Date

2. **General research results (such as number of participants in the study, combined preferences for receiving incidental findings, 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



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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 cancer, genetic diseases, the usefulness of genomic sequencing or people's preferences for learning incidental findings. Data might be shared with researchers who want to learn about the usefulness of genomic sequencing information, or about how people feel about learning genomic sequencing information, 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.

**You may participate in the study without agreeing for us to share your research results/study data with other researchers. Please indicate your choice below.**

I do **not** give my permission for my research results/study data to be shared with other researchers.

I give permission for my research results/study data to be shared with other researchers.

\_\_\_\_\_  
Participant's Name

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

**WILL FAMILY DOCTORS/GENERAL PRACTITIONERS KNOW WHO IS PARTICIPATING IN THIS STUDY?**

Your family doctor / general practitioner may be informed that you are taking part in this study, as well, unless you choose to inform them yourself.

If you have results that are negative, inclusive or do not need any referrals, we will not share these results with your general practitioner / family doctor. However, you can share your results with your general practitioner / family doctor if you wish to do so. If you have results that require a referral for follow up testing with a specialist, we will, with your permission, send a copy of your results to your general practitioner / family doctor. We would like to do this as it may be important for your general practitioner / family doctor to know what actions are being taken regarding your health. Sharing these types of results with your general practitioner / family doctor is not mandatory, you can decide not to share this information if you wish.

I do **not** give my permission for results that requires referral to be shared with my general practitioner / family doctor

I give my permission for results that requires referral to be shared with my general practitioner / family doctor.

\_\_\_\_\_  
Participant's Name

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

You results may require follow up in other specialist clinics, in which case referrals will be made to the healthcare providers in those clinics. The genetics clinic where you were being seen for your cancer diagnosis will make and manage referrals to specialist clinics.

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As we stated earlier, as part of this study we would like to access your medical records and your family history from the clinic that referred you to this study. This information is necessary so we can better analyze your DNA sample.

**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 on line.

**WHAT ARE THE COSTS TO PARTICIPANTS?**

You will not be charged for your participation in this study. We will cover the costs of the genomic sequencing and procedures (e.g. saliva sample) related to 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 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 samples and/or 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.

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

By signing this form you do not give up any of your legal rights against the study doctor, sponsor or involved institutions for compensation, nor does this form relieve the study doctor, sponsor or their agents of their legal and professional responsibilities.

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

**WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT A RESEARCH PARTICIPANT?**

If you choose not to learn about certain types of results, we will not disclose them to you against your wishes. Otherwise, any results you choose to receive will be revealed to you.

**WILL I BE CONTACTED AFTER I HAVE COMPLETED THE STUDY?**

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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 decision aid or genetic counselling parts of this study, how information about incidental findings was communicated to you, 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 results of genomic sequencing in the long term. We may contact you to invite you to participate in other studies related to the topic of genetics and genomic sequencing. 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 principle 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 and that conforms to all privacy and confidentiality laws. Only study staff will 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.

I give permission to be contacted by study staff in the future.

I do not wish to be contacted by study staff in the future.

\_\_\_\_\_  
Participant's Name

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

### 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 Ph.D., Principal Investigator, 416-864-6060 x 77378
- Marc Clausen, Research Coordinator 416-864-6060 x 77397

#### *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 416-864-6060 ext. 2557

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**VERBAL INFORMED CONSENT FOR Genetics Adviser: evaluating a digital decision support tool for genetic results****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
<b>Voluntary</b>			
1. Does the participant agree to participation in the research study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Once they have verbally consented, does the participant have to stay in the research study until the end?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. If they decide not to consent to the study, will the way health care providers feel about the participant change in any way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>About the Research Study</b>			
4. What is the purpose of the study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Risk and Benefits</b>			
5. What are the benefits of being in the study for the participant?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. What are the risks of being in the study for the participant?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Confidentiality</b>			
7. Will the participant's study files be kept confidential?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Time Required</b>			
8. How long will the participant be required to participate in this study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Reimbursement</b>			
9. Will you or the participant be paid for taking part in this study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Questions</b>			
10. If the participant has specific questions about this study, who should they ask?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. If the participant has questions about being involved in a research study in general, who should they ask?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Medical Records and DNA Sample Access</b>			
12. Will the participant's medical record be accessed and for what reason?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Does the participant agree to have their genomic sequencing results shared with the genetics clinic where they were being seen for your cancer diagnosis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Does the participant allow the study team to re-analyze their exome sequence from the Incidental Genomics Study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Does the participant agree share any results needing referral with their General practitioner / family doctor?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Does the participant agree to have genomic sequencing performed on their DNA sample if necessary?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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17.	Do Intervention participants understand that the decision aid data will be stored in the United states and are therefore subject to USA privacy laws while being stores in the USA.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<b>RESPONSE TO CONSENT OPTIONS</b>		
		<b>YES</b>	<b>NO</b>	
<b>Sharing Results and Data</b>				
18.	In the event that the participant dies before they receive their genomic sequencing results, do they give permission for the study staff to share any life threatening genetic results with their designated family member?	<input type="checkbox"/>	<input type="checkbox"/>	
19.	Does the participant give permission for their raw genomic sequence and phenotype information to be shared with other researchers and uploaded to genetics data sharing databases?	<input type="checkbox"/>	<input type="checkbox"/>	
20.	Does the participant give permission for their research results/study data to be shared with other researchers?	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Permission for re-contact</b>				
21.	Has re-contact been explained? Does the participant agree to being re-contacted by study staff?	<input type="checkbox"/>	<input type="checkbox"/>	

**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

\_\_\_\_\_  
Signature of Person Conducting

\_\_\_\_\_  
Date and Time (24h clock)