Informed Consent Form for Participation in a Research Study

Study Title: OurGenes Study

Study Doctors:

Dr. Raymond Kim, Medical Geneticist
University Health Network
610 University Ave., 700U-6W390
Toronto ON, M5G 1Z5
Tel: (416) 946-4501 ext. 2293

Dr. Ari Morgenthau, Endocrinologist
University Health Network
200 Elizabeth St., 12EN Room 215
Toronto ON, M5G 2C4
Tel: (416) 340-3772

Sponsor/Funders: University Health Network

Contacts:
For non-emergency questions, contact the Research Study Team:

- Email: OurGenes@uhn.ca
- Phone: (437) 676-3576

**Please note that communication via e-mail is not absolutely secure. Thus, please do not communicate personal sensitive information via e-mail.*

A person who takes part in a research study is called a research participant, or study participant. In this consent form, "you" always refers to the research participant.

INTRODUCTION

You are being invited to participate in a research study offered at the University Health Network (UHN). This consent form provides you with information to help you make an informed choice about your participation in this study. Please read this document carefully and reach out to the research team about any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study. You may find it helpful to discuss it with your friends and family.

Please take your time in making your decision. Taking part in this study is voluntary. You have

the option to not participate at all, or you may choose to leave the study at any time. Whatever you choose, it will not affect your usual medical care that you receive outside the study. Before signing, contact a research team member if you have any further questions about your participation.

Please note, in order to participate in this study, you must be at least 18 years of age and be a resident of Ontario.

You must not have any of the following due to blood DNA not being a reliable source for the study:

- Had an allogeneic ("donor") bone marrow/stem cell transplant
- Active hematologic (blood) cancer/condition, such as leukemia, lymphoma, myelodysplastic syndrome (MDS) or myeloproliferative neoplasm (MPN) (*Note: If you have a history of one of these conditions, you can still join if you have completed treatment and are in remission.)*

IS THERE A CONFLICT OF INTEREST?

The researchers have an interest in completing this study. Their interests should not influence your decision to participate in this study. Data from this study may be used for UHN and non-UHN research or to create new products. UHN may also benefit financially from the sharing of participant data in the future. Any money made from this data sharing would only go to UHN. Any money will be used to further UHN's objectives as a not-for-profit health care institution. None of the study team will receive financial benefit from the study.

WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?

Deoxyribonucleic acid (DNA) is the genetic information inside the cells of our body. It is the instruction manual telling our body how to develop and function. Individuals with certain genetic conditions are born with changes in their DNA that increase their risk for various health issues. As a result, they sometimes need more frequent health screenings and preventive measures.

The US Centers for Disease Control and Prevention (CDC) identifies three genetic conditions where treatments and interventions have potential to significantly reduce illness and death: hereditary breast and ovarian cancer syndrome (HBOC), Lynch syndrome, and familial hypercholesterolemia. HBOC, specifically involving the *BRCA1* and *BRCA2* genes, increases the risk of developing breast, ovarian, pancreatic, prostate and other cancers. Lynch syndrome is the most common cause of hereditary colorectal cancer. People with Lynch syndrome are more likely to get colorectal cancer at a younger age and are also at an increased risk of developing endometrial, ovarian, upper GI, brain, pancreatic and/or other cancers. Familial hypercholesterolemia is an inherited form of very high cholesterol that causes heart disease at an earlier age than the general population.

Currently, these conditions are not well-identified by the health care system, leaving many individuals and families unaware of their risk. If people have the opportunity to learn their genetic risk for certain conditions, this can help them and their health care providers make decisions about extra screening and/or risk-reducing surgeries.

To address this, US-based Helix Inc. ("Helix") has created a health program to collaborate with health care organizations on large-scale genetic research and health care services and return genetic screening results related to the three CDC conditions described above to you. UHN is the first Canadian organization to join this program. Helix is a company that specializes in analyzing genetic information. They can read your genetic information (DNA) from a sample of your blood. Helix will study your DNA using whole exome sequencing or whole genome sequencing. Whole exome or genome sequencing is a way of studying your genes, which are the parts of your DNA that instruct your body on how to function. By examining your DNA, we can identify any genetic changes that might affect your health.

Helix also studies the DNA of large groups of people to learn how genes vary across different populations, which helps scientists understand how certain genes affect health and disease.

WHY IS THIS STUDY BEING DONE?

The study is being conducted to improve the detection of people with hereditary breast and ovarian cancer, Lynch syndrome, and familial hypercholesterolemia through genetic testing.

This will enable the OurGenes study team and Helix to:

- To return individual results about your DNA to you, your health care providers, and researchers to better understand how your DNA might impact your health, both now and in the future.
- Combine your genetic information with the information from your health records which may support research to discover the underlying causes of disease, to help understand who is at risk, what steps can be taken to prevent disease, and what treatments may work best for patients.
- To establish a research network called the Helix Research Network, allowing for UHN researchers, other researchers and health care companies to work together to share information and study human health through DNA research. Your personal health information (PHI) from UHN will be shared with Helix, including demographics and medical history, on an ongoing basis over a 10-year period. This data will be stored in the Helix Research Network indefinitely and may be shared with other organizations for health research.

WHAT OTHER CHOICES ARE THERE?

Whether or not you choose to participate, it will not impact the care you receive at UHN. Your

decision to not take part will not result in any penalty or loss of benefits and will not affect the medical care or benefits to which you are otherwise entitled. If you decide you do not want to participate in this research study, you may still participate in other studies.

Depending on your personal and family history, there may be other clinical genetic testing options available to you. You can speak with your health care provider to request a referral to a genetics clinic to learn more. For a personal and/or family history of cancer, a referral can be sent to the Bhalwani Familial Cancer Clinic at Princess Margaret Cancer Centre (UHN). For a personal and/or family history of other hereditary conditions, a referral can be sent to the Fred A Litwin Family Centre in Genetic Medicine at UHN. A list of all genetics clinics in Ontario is also available here.

The testing offered through this study has limitations and is not intended to replace more comprehensive clinical testing ordered by your health care provider. If you have a family history of cancer or high cholesterol, please speak with your health care provider about your options for genetic testing as well as the results provided by the OurGenes Study.

This research study might reveal genetic information about you or your family that you were not previously aware of.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that about 100,000 people from UHN will take part in this study. The study will take up to 10 years to complete.

WHAT WOULD I NEED TO DO TO PARTICIPATE IN THE STUDY?

You will provide a blood sample for DNA sequencing. Sequencing is the process of reading the letters of your DNA. Once you have given us your sample, your participation will not take a lot of your time. The research team will collect health information about you from your medical record. If you choose to enroll, you will be part of this study until you withdraw or until the study ends.

- A small tube of blood (about 4 mL or 1 teaspoon) will be collected at the hospital laboratory.
- After signing this consent form, you have 6 months to provide a sample.
- You may be asked to provide repeat samples if there are technical issues with the original sample.
- These blood samples will be sent to the Helix laboratory at San Diego, California where they will be examined.

Ongoing Sharing of your UHN PHI with Helix

Your electronic health data from your UHN health record will also be shared with Helix. This includes all the information in your medical file such as demographics (e.g. date of birth, sex, ethnicity and partial postal code), all information about your current and future medical history (e.g. UHN visit dates, medical diagnoses, medical test results, surgery information, and prescription information). This data will be stripped of direct identifiers and coded, meaning that directly identifying information (such as your name and date of birth) will be replaced by a number, ensuring the information is no longer linked to you directly. This data will be collected and updated every 3 months during your participation and sent to Helix. This data will be stored in the Helix Research Network (HRN).

Use and Sharing of your PHI by Helix

The Helix Research Network supports a wide range of research to understand and improve health. The Helix Research Network studies how diseases work and how to treat them better. They use genetic and real-world data to find disease markers (indicators of disease), predict health outcomes, and test new treatments. If you choose to enroll, your data will be stored in the Helix Research Network indefinitely. Data could be shared with other organizations to do health related research. However, data will not be available to insurance companies in any form for any research.

The collection of blood samples is a necessary part of this study. Once these tests have been completed, blood samples are discarded after 90 days. Any leftover DNA samples will be stored within the Helix laboratory (located in San Diego, California, US) for up to 25 years.

The main reason DNA is stored is to help with future genetic tests if necessary. By storing these samples, we can revisit them for additional tests or analysis if needed. DNA samples are not used for future research.

You will receive these results in two ways. First, these results will be returned to your UHN medical record. You cannot opt out of having your DNA health results placed in your UHN medical record. You may access this information by speaking with your study doctor, and/or via myUHN (the UHN patient portal). Once this information is in your medical record, it cannot be removed, even if you withdraw from the research study. Second, you will also be able to access these results through your Helix Account, if you choose to create one. There may be a delay between when your results are available in your medical record and when you are able to access them through your Helix account.

Creating a Helix Account is completely optional and is not considered to be a part of the OurGenes Study. More information about this Helix Account can be found on the Helix Account Information Sheet, which will be sent to you directly after you have consented to participate in the OurGenes Study.

<u>WHAT HAPPENS IF I AM FOUND TO HAVE A GENETIC VARIANT?</u>

Approximately 1-2% (one to two people out of 100) of participants will be found to have a genetic variant that increases their risk for the causes of hereditary cancer or very high cholesterol included in this study. These genetic variants are sometimes called gene 'mutations'. A gene mutation is a change in a gene that stops the gene from working as it should. Gene mutations are often passed down in families, from one generation to another.

If you are found to have one of these gene mutations, you will be scheduled an appointment to speak with a genetic counsellor or other health care provider at UHN to discuss your result further. This provider may refer you to other specialists based on your genetic result.

HOW WILL SAMPLES BE IDENTIFIED?

Your samples will be sent to Helix and will be labelled with your name, date of birth and your UHN medical record number (MRN).

CAN I WITHDRAW FROM THE STUDY?

You may withdraw your consent to participate in the Helix Research Network (HRN) at any time. Declining to participate in HRN will not impact your health care or relationship with UHN. Your decision to withdraw will not result in any penalty or loss of benefits and will not affect the medical care or benefits to which you are otherwise entitled.

To withdraw, please contact the OurGenes study team by email at OurGenes@uhn.ca or by phone at (437) 676-3576. You can specify if you would like to withdraw from any ongoing participation and/or withdraw any past data and samples that were shared with Helix and stored in the US-based Helix Research Network (HRN) database. The study team will then reach out to Helix to process the withdrawal request.The study team will then reach out to Helix to process the withdrawal request.

If you withdraw from the study, you will no longer receive any emails or other communication as part of the study. The study team at UHN will also stop providing Helix with any new data and/or updates to existing data once you request to withdraw from the study. If you withdraw from the study, you will no longer receive any emails or other communication as part of the study. The study team at UHN will also stop providing Helix with any new data and/or updates to existing data once you request to withdraw from the study.

After you have withdrawn from Helix, your data will not be used in new studies or research projects. However, active/ongoing and completed research projects by Helix and other non-UHN studies may continue to use any data that has previously been collected. Helix will remove withdrawn participants from the HRN dataset.

Any information that has already been added to your UHN medical record will remain in your UHN medical record. However, no new information from the study will go into your medical

record. If tests have already been done on your sample(s), it will not be possible to withdraw those results from your UHN medical record. However, no further testing will be done.

Additionally, you may ask us to delete your information stored in the HRN dataset and destroy any stored samples. Any information and samples that Helix has stored that are linked to you will be deleted, although it may take some time for this request to be processed and fulfilled. If this is the case, we will let you know. This will not impact or delay your withdrawal from the study.

CAN MY PARTICIPATION IN THIS STUDY END EARLY?

You may be taken out of the research study for any reason including:

- You are unable to provide a blood sample
- If you do not provide a sample within the required time frame
- If the sample(s) you provide are not able to be successfully analyzed
- You are deemed ineligible by the study doctor to participate in the study
- Helix decides to stop the study
- The UHN Research Ethics Board withdraws permission for this study to continue
- Other unforeseen reasons that make it necessary to stop your participation in the research study

If you are removed from this study, the study doctor will discuss the reasons with you and plans will be made for your continued care outside of the study.

WHAT WOULD MY RESPONSIBILITIES BE AS A STUDY PARTICIPANT?

By consenting to this research study, you will be asked to:

- Provide a blood sample
- Be available via myUHN or have a valid mailing address to receive results from the research study

HOW LONG WILL I BE IN THE STUDY?

Study recruitment will continue for up to 5 years. UHN will be actively collaborating with Helix for up to 10 years. In terms of your genetic and health information, versions of this information stripped of direct identifiers will be stored indefinitely in a database as part of ongoing analysis in the Helix Research Network (HRN). Helix or external researchers will not have access to your UHN medical records. Instead, our study team will provide Helix with the necessary health information, which will be included within the HRN as coded data. If you no longer visit UHN for your health care, your samples and information will remain with Helix unless you withdraw from the study (see above for more information about options to withdraw from the study).

If you do not want your information to be used for this type of research, you should not

participate in this study. In most cases, because the results from this type of research stripped of direct identifiers will not directly affect your personal health care, we are unable to share the individual results from future studies with you or your health care provider.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

Blood Collection Risks:

There is a physical risk associated with blood collections, including potential for bleeding, bruising, discomfort, infections or pain at the needle site, or dizziness from the needle to take the blood samples.

Risks Associated with Genetic Testing:

Despite UHN and Helix implementing strict privacy and security measures to protect the privacy of your information, there is always a chance that your genetic data, health information, and/or personally identifying information may be compromised in the event of a security breach.

There is the potential loss of your privacy and the loss of confidentiality of your personal health information. While the databases developed for this study will not contain direct identifiers, future technological advances might make re-identification possible to link your genetic or medical information in our databases back to you or your family members. Even with protections in place, absolute confidentiality cannot be guaranteed. Advances in technology could also increase the risk that your genetic samples and results could be linked back to you or your relatives. There is no way to predict what effects such an information loss would have. For example, if an insurer, a current or future employer, or law enforcement were to learn your genetic code, it could result in loss of privacy and to possible future discrimination in employment or insurance against you or your relatives. Even though this risk is unlikely, we think you should be aware.

Due to the rapid pace of technological advances, the potential future use of genetic information is unknown and therefore the potential future risks also are unknown and there may be a risk that the genetic information in the samples could be linked back to you.

Risks Associated with Data Sharing:

The more data you contribute to the Helix Research Network, the easier it becomes for someone to identify you from this data. Although Helix takes the protection of your privacy very seriously and has implemented reasonable effort to keep your information safe, it cannot be guaranteed that your information will be kept private. However, the risk of information being shared or used inappropriately is considered to be small.

There are potential risks associated with receiving actionable genetic results that may reveal a risk of you and/or your family developing certain conditions. This knowledge may cause your or your family stress and may impact how you decide to manage your health, as well as how your relatives manage their health.

Risks Associated with Data Storage Outside of Canada:

Your health and genetic information will be housed in the USA. Any information and/or samples, sent outside of Canadian borders may increase the risk of disclosure of information because the laws in other countries dealing with protection of information may not be as strict as in Canada.

The study samples will be labelled with your name, date of birth and medical record number (MRN) until they reach the Helix genetics laboratory in San Diego, California. Once your sample has reached the Helix laboratory, your identifiers will be removed from the sample and replaced with a code that is unique to you. This unique code is used by the Helix laboratory staff to track your genetic test results and re-identify them once the laboratory processes have been completed.

This unique code is also used to store your sample in the Helix laboratory storage area. These samples will not be used for future research studies but may be used for quality improvement within the Helix laboratory.

The personal information and data collected during the consent process and from participating in this study will be stored on computer systems in the United States (US). When study information is transferred to the US, it is subject to foreign laws. These laws differ from those of Canada, including the USA Patriot Act, other laws and regulations, and potential future Executive Orders. Under US law, US government agencies may access your personal information and health care data without your knowledge or consent. Helix may also be required to disclose your information to governmental authorities under different circumstances than those in Canada. If Helix is notified that your personal information has been accessed due to this law, UHN will be notified. If you have questions about the storage of your information in the United States, please speak with the research team.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

There is a chance that researchers might find information that could be important to your health. Over time, it is possible that other results will be made available to you. Some of this information could also have an impact on your health. There is also a chance that information you learn could impact the health of your family members. You may learn information from the study that may immediately impact your or your family's health care. You may learn if you have inherited certain risk factors in your DNA. This information may allow you to screen for, prevent, or minimize the impact of familial hypercholesterolemia, hereditary breast and ovarian cancer syndrome, and Lynch syndrome. If you are found to have a genetic change in your DNA, you will be scheduled to speak with a genetic counsellor or other health care provider at UHN to discuss the impact this may have on your and your family's health.

HOW WILL MY 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.

Your data will be shared as described in this consent form and/or as required by law and/or applicable research regulations. Records identifying you at UHN will be kept confidential and, to the extent permitted by applicable laws, will not be disclosed or made publicly available.

Authorized representatives of the University Health Network including the UHN Research Ethics Board, who oversees the ethical conduct of this study at UHN, may come to the hospital or be given remote access to an electronic portal (via Internet) to 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. When using the electronic portal, we will share your medical record number using a secure method, so that your records are included as part of their review. These individuals have completed privacy training and signed confidentiality agreements and/or are required by law to keep your information confidential.

Whether on-site or remotely, UHN makes all efforts to ensure that your information is shared in a way that is secure and private (encrypted). However, any electronic communication carries some risk of third parties gaining unauthorized access to information.

The following companies will receive your personal identifying information (e.g., name, full date of birth, MRN) to support your participation in this study and the return of your genetic screening results. Helix has strict security and privacy measures in place with these companies to protect your information.

- Hubspot: Customer Support Case Management
    - Hubspot will store your personal identifying information **indefinitely**.

- Ketch: Processing of Withdrawal Requests
    - Ketch will store your personal identifying information **indefinitely**.

- Amazon Web Services (AWS): Secure Cloud Services Platform
    - AWS will store your personal identifying information **indefinitely**.

- Redox: Middleware Software (i.e. a type of software that helps different systems talk to each other)
    - Redox will store your personal identifying information for 90 days.

- Iterable: Platform for Multi-Factor Authentication During Consent Process
    - Iterable will store your personal identifying information for 60 days.

Additionally, the following organizations may receive study data:

- Contractors of Helix who are contracted to perform research activities.
- Other Helix Research Network member organizations.

Your data will be stored in the US. Once data is stored in US databases, you are no longer under Canadian protections. The data is under the protection of US privacy laws.

Your samples will be stored in a secure laboratory facility at Helix.

This study requires the transfer of identifiable information (name, date of birth and MRN) to Helix for the purposes of labelling your samples and ensuring that your genetic report also has your identifying information on it.

If the results of this study are published, your identity will remain confidential. Researchers plan to publish the results of their research. As part of the publication process, researchers may be asked to make certain information available to other researchers. Helix or the OurGenes study team will not include information that directly identifies you in any publications.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

- We will tell you if there is a data breach that impacts your information
- All researchers go through an approval process before gaining access to your information. The lead researcher for the study (the Principal Investigator) will participate in a committee that includes researchers from other health systems that do similar research. This committee is responsible for setting standards for access to your information.

The study doctor at UHN will keep any study-related records in a secure and confidential location for at least 10 years from the completion of the study. Your study-related records will be stored by Helix indefinitely.

Your participation in this study will also be recorded in your medical record at this hospital. This is for clinical safety purposes.

WHAT RESEARCH INFORMATION IS STORED IN MY SHARED CLINICAL RECORDS?

If you participate in this study, information about you from this research project may be stored in your hospital file and in the UHN computer system. UHN shares 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. The study team can tell you what information about you will be stored electronically and may be shared outside of the UHN. If you have any concerns about this, or have any questions, please contact the UHN Privacy Office

at 416-340-4800 x6937 (or by email at privacy@uhn.ca).

HELIX RESEARCH NETWORK: STORING YOUR DATA FOR ONGOING ANALYSIS

Your coded study data will be used or shared with other researchers (both inside and outside of Canada) for ongoing research and analysis. "Coded" means that directly identifying information (such as your name and date of birth) will be replaced by a number, which will be applied to the study data. The code matching your study data and samples with your name and other directly identifying study data will be kept by Helix indefinitely, unless you withdraw your consent.

Helix will store your personal identifying information (e.g., name, full date of birth, and MRN) separately from the HRN database indefinitely. This is to accurately identify and delete data for withdrawing participants, conduct future diagnostic tests requested by your health care providers, and comply with regulatory audits.

CONTROLLED-ACCESS AND OPEN ACCESS DATABASES

The coded study data and/or samples may be stored in:

- Controlled-access databases/biobanks. Access to them is limited to researcher(s) who submit a study plan and who sign an agreement to use the coded study data only for that research.
- Open access, publicly accessible databases. Only very limited coded study data may be placed in such databases. The goal of sharing is to make more research possible.

One such controlled-access database is the Helix Research Network. The coded data that will be shared with Helix includes demographics (such as year of birth, sex, ethnicity and partial postal code) and information about your medical history (such as UHN visit dates, medical diagnoses, surgery information, and prescription information). Once this coded data is in the Helix Research Network database, access to this data is limited to researchers who submit a study plan and who sign an agreement to use the coded study data and/or coded samples only for that research. If approved, these researchers may have access to coded data in HRN for a variety of research purposes. For example, researchers may use this data for drug discovery, to determine the genetic determinants of a particular disease, to review the impact of genetic test results at population scale, or to investigate care gaps within the member hospital systems.

In addition, Helix shares data about genetic variants and their clinical significance with ClinVar, a public archive that links genetic variants to health conditions, as well as dbGaP, a database that stores results from studies about the relationship between genetic variants and observable traits. Any public-facing data shared by Helix is de-identified and is shared at a summary level only.

You will not be asked if you agree to take part in additional future research studies within the Helix Research Network using your study data, nor in any other open or controlled-access

databases to whom Helix may transfer your data. You or your study doctor will not be told what type of research will be done. You will not be given reports or other information about any research that is done with your study data.

WILL I BE CONTACTED ABOUT ADDITIONAL RESEARCH OPPORTUNITIES?

In some cases, the UHN study team may contact you to get more information or to ask if you are interested in participating in additional research studies. Participation in additional studies is always optional. Any time you are re-contacted by the study team you may choose not to participate, and it will not affect your overall participation in this study. If you consent to creating the optional Helix Account, Helix may contact you for additional research opportunities outside of the OurGenes Study and not connected to UHN.

WILL MY HEALTH CARE PROVIDERS KNOW THAT I AM PARTICIPATING IN THIS STUDY?

Your external non-UHN family doctor/health care provider will not be notified directly by the study team that you are taking part in the study. You can choose to let your family doctor/health care provider know, if you like. Members of your UHN health care team will be able to see that you are participating in the OurGenes Study, but this will not impact your clinical care in any way. If medically relevant results are found from this research study, your family doctor and/or other health care providers may be informed.

WILL INFORMATION ABOUT THE RESULTS OF THIS STUDY BE AVAILABLE?

Study results will be shared with you if/when they become available after this study is completed. It is expected that this may take a number of years. The results will be shared with you based on your preferred communication method indicated in UHN's medical record system. Please talk to your study doctor if you have any questions about the results.

WHAT IS THE COST OF THIS STUDY?

Participation in this study will not involve any additional monetary costs to you.

WILL I BE PAID TO BE IN THIS STUDY?

You will not be paid for taking part in this study.

IS THIS STUDY BEING USED FOR COMMERCIALISATION?

We may use your samples and information to develop new products or medical tests to be sold. Helix and UHN may benefit if this happens. There are no plans to pay you if your samples are used for this purpose. It is possible that researchers and their organizations may benefit from the sharing of the information or sale from the discoveries they make. You will not have any

financial or other rights to these discoveries.

WHAT ARE MY RIGHTS AS A RESEARCH PARTICIPANT?

You will be told about new information that may be relevant to your willingness to stay in this study.

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.

WHAT IF RESEARCHERS INCIDENTALLY DISCOVER SOMETHING UNEXPECTED ABOUT ME?

In genetic research, researchers sometimes learn something about you that they didn't expect. For example, the researchers may find that you carry a genetic variant that may increase your chance of developing a different medical condition that was not outlined in this consent form. This is called an incidental finding. Incidental findings are information that was discovered unintentionally. We are not looking for these types of findings, and the chance that an incidental finding is identified through this study is low; however, it is possible. If we discover an incidental finding that is medically actionable (meaning, there is a high chance of a health problem and treatment and/or screening is available for this health problem), you or your delegate may be contacted to inform you about this. Any incidental finding identified through this research study would need to be validated in a medical-grade laboratory. In addition, you would be offered a referral to a local medical genetics' clinic, where a genetic counsellor would review this finding with you in detail.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study or suffer a research-related injury, you can talk to your study doctor. That person is:

Dr. Raymond Kim	(437) 676-3576
Name	**Telephone**

If you have questions about your rights as a participant or about ethical issues related to this study, call the Chair of the University Health Network (UHN) Research Ethics Board (REB) or the Research Ethics office number at 416-581-7849 (or by email at reb@uhn.ca). The REB is a group of people who oversee the ethical conduct of research studies. The UHN REB is not involved in the conduct of the study. Everything that you discuss will be kept confidential.

You will be given a copy of this signed and dated consent form prior to participating in this study. A copy of the consent form that you sign to enter the study will be included in a research record within your health record/hospital chart.

CONSENT

- All of my questions have been answered.
- I allow for the ongoing disclosure of information from my health records to Helix for a 10-year period, along with relevant specimens.
- I understand that Helix will store this information in the United States for future research studies and may share it with open and controlled-access databases as described above.
- If medically actionable results are found from this research study, my family doctor or other health care provider(s) may be informed.
- I am aware of the risks of sample collection, genetic testing and data sharing as discussed in this consent form.
- I agree to take part in this study.
- I authorize UHN and Helix to share my health information with any entity or contractor engaged by Helix to support the research.