# Study Information and Informed Consent Form

**Ontario Hereditary Cancer Research Network: OHCRN**

Trial Code/study #: *OHCRN*

**Study Doctor:** Dr. Raymond Kim

**Sponsor:** Ontario Institute for Cancer Research

Non-Emergency contact numbers are at the end of this document in the "Where can I get more information?"

When we say 'you' in this consent form, we mean you or your child; 'we' means the doctors and other study staff.

## Overview and Key Information

### 1. What am I being asked to do?

We are inviting you to take part in a research study that will create the Ontario registry for hereditary cancers, as part of the Ontario Hereditary Cancer Research Network or OHCRN.

You are invited to participate because you have a known or suspected hereditary cancer predisposition syndrome and have undergone germline genetic testing.

### 2. Taking part in this study is your choice.

You can choose to take part, or you can choose not to take part in OHCRN. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered. See the "Where can I get more information" section.

### 3. Why is this study being done?

Individuals with hereditary cancer syndromes (HCS) are born with a genetic mutation (abnormal change in their genes). Genes are the basic unit of heredity passed from parent to child. Individuals with HCS are at a high risk of developing cancers in their lifetime and would benefit from intensive life-long surveillance through genetic testing and intervention at the most appropriate time.

Currently, genetic testing is being conducted at several Ontario cancer genetic laboratories and the results of the testing, along with patient clinical information, is found at multiple centres across the province.

We are establishing this registry because we want to create a centralized system that will collect clinical and genetic information from patients with hereditary cancer across Ontario.

The data collected within the Registry will be shared with researchers and will be used for various research purposes, including research facilitated by linkage to administrative health databases, which may inform the creation of appropriate surveillance programs for those with HCS. This single provincial registry and the use and sharing of the data collected through the registry will help to improve and enhance patient care for individuals in Ontario with hereditary cancer.

## 4. What is the standard of care for my hereditary cancer syndrome?

The standard of care for patients with a hereditary cancer syndrome involves confirmation of results by genetic testing, followed by intensive life-long surveillance, potentially involving multiple specialists across the province. This study does not include treatment or management options for your HCS.

## 5. What are my choices if I decide not to take part in this study?

- You may choose to have the standard of care described above without being in this study.
- You may choose to take part in a different research study, if one is available.

You may talk to your study doctor or usual doctor about the known benefits and risks of these other options before you decide about taking part in OHCRN.

## 6. What will happen if I decide to take part in this study?

If you decide to take part in OHCRN registry, you can access the study through a patient portal link on the website (www.OHCRN.ca) and self-enroll, by following the steps within the patient portal link. This would include creating an account by providing some of your information.

You must consent to the release and ongoing collection of your clinical and genetic data from the institutions that are custodians of your data to be added to the OHCRN Registry. The consent form will be accessible for you to review and sign, once you have created your account on the patient portal.

Information will be collected from your medical records, which may include clinical reports, pathology reports, and laboratory files. Information may also be collected through linkage to Provincial administrative health databases, using your OHIP number.

Your data will be collected in a database which will be stored on the OICR servers using secure methods. The creation of this registry has no determined end date. The data will remain in the registry for as long as the registry is active. If funding for this research projects ends, the OHCRN registry will be discontinued and other data collection will stop.

## 7. What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

**Risks**
We want to make sure you know about a few key risks right now. You can find more information in section 12: "What risks can I expect from taking part in this registry?"

If you choose to take part in OHCRN, there is a risk of the disclosure of personal health information to an unauthorized party. There are no physical risks associated with inclusion in this registry. There may be some risks that the study doctors do not yet know about.

**Benefits**
This registry may help the study doctors learn things that may help other people with HCS in the future. OHCRN may benefit patients with a hereditary cancer syndrome across Ontario by consolidating their clinical and molecular information into one centralized location. It is anticipated that this will have a direct benefit on patient care.

## 8. If I decide to take part in this study, can I stop later?

You may withdraw your consent to take part in the registry at any time by letting the study doctor or member of the study team know as soon as possible.

You can choose to temporarily pause or inactivate your account and stop ongoing data collection for the OHCRN registry. Your data that was recorded before you inactivated your account will be kept and shared with researchers, but no new information will be collected. You will not be asked to take part in any ongoing activities, but we may still contact you regarding your profile, data, consent, and privacy. You will still have access to your profile and will be able to reactivate your account to allow or resume ongoing data collection again. When you reactivate your account, we will collect any missing data, including information generated while your account was paused.

Alternatively, you can choose to withdraw from the study completely. OHCRN will no longer contact you and your data will be removed from the registry. Your information will no longer be accessible to researchers. It will not be possible to destroy any information already provided to researchers. A minimum amount of information will be retained for auditing purposes (including first name, last name and date of birth).

Your study doctor will tell you in a timely manner about new information or changes in the study that may affect your health or your willingness to continue in the registry.

## 9. Are there other reasons why I might stop being in the study?

Your study doctor may take you off the registry if:

- New information becomes available, and the registry is no longer in your best interest.
- You are unable to complete all of the requirements for study participation.
- Approval for the registry is stopped by the Research Ethics Board (REB), or study sponsor (Ontario Institute for Cancer Research). The study sponsor is the organization who oversees the study.

---------- End of Overview Section ----------

**It is important that you understand the information in the Informed Consent Form before making your decision.** Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask a member of your care team.

## 10. What is the purpose of this study?

The purpose of this study is to create a centralized registry for individuals (children and adults) in Ontario with a known or suspected hereditary cancer syndrome who have undergone germline genetic testing.

This centralized registry will be used to collect clinical and genetic information for individuals with hereditary cancer. Information will be kept in one centralized location with the aim of improving patient care and facilitating research.

## 11. What exams, tests, and procedures are involved in this study?

There are no additional procedures required as part of OHCRN registry. Once you provide your consent to join OHCRN, a member of your circle of care or a member of the study team will confirm your eligibility to participate by reviewing the results of your exams, tests, and procedures. If you join the registry, you will still follow regular standard of care as prescribed by your health care team.

The following procedures are required as part of this study:

- Collection of your personal and Health Information through the review of your medical records; health information will include past, present and future information that is relevant to your hereditary cancer diagnosis and other health conditions, including for example, results of genetic, pathology and molecular tests.
- Your study data that will be included in the database will be identified by your study ID. Personal health information/identifying information will be identifiable to members of the OHCRN study team.
- Your data may also be used to link to other existing provincial administrative health databases. To do this, you will need to provide your OHIP number.
- Your de-identified data may be given to researchers for ethics approved research studies. Aggregate data (de-identified) may be displayed on the OHCRN website for research use and is visible to the public.

## 12. What risks can I expect from taking part in this study?

**General Risks**

If you choose to take part in this registry, there is a risk of inappropriate release of confidential data. In the event of inappropriate release of personal health information to an unauthorized party, further release of information will be stopped and there will be an attempt to retrieve information. The Ontario Cancer Research Ethics Board (OCREB), as well as any subsites directly affected will be notified and further actions may be taken according to the recommendations of OCREB. There are no physical risks associated with OHCRN.

## 13. What are the costs of taking part in this study?

There are no associated costs for participating in the registry.

You will not be paid for taking part in the registry. The research using data in the registry may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

If you choose to be told about genetic results that are found as a result of additional research studies, associated with the registry in which you agree to participate, results will need to be confirmed in a laboratory that is not associated with OHCRN. These tests may not be covered by your provincial health care plan and may only be available if you or your private insurance pay for them.

## 14. Who will see my medical information?

Your privacy is very important to us. Every effort will be made to protect it. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

There are organizations and their representatives that may look at or receive copies of some of the information in your study records for data analysis and quality assurance. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

Some of these organizations are:

- The study sponsor Ontario Institute for Cancer Research and any company supporting the study now or in the future. This would include any organization helping the sponsor with the study.
- The Ontario Cancer Research Ethics Board (OCREB), which is a group of people who review the research with the goal of protecting the people who take part in the study.

In addition to storing data in the registry, data from studies that are publicly funded may also be shared for future use in public databases with protections for your privacy. The goal of this data sharing is to make more research possible which may improve people's health. Your study records may be stored and shared for future use in other provincial health databases, including datasets accessible via the Ontario Health Data Platform [OHDP] and the Ontario Cancer Registry. Your name or other personal information that may identify you will not be disclosed.

Data that has had your personal information removed may also be shared with approved researchers, including those internationally, who may be affiliated with a range of institution types, including academic, charitable organization, hospitals, industry, and for-profit companies (such as drug companies).

Some types of future research may include looking at your information and information from other participants across many studies or comparing new study data with other study data. However, right now we don't know what research may be done in the future using your information. This means that:

1. You will not be asked if you agree to take part in the specific future research studies using your health information.
2. You and your study doctor will not be told when or what type of research will be done.
3. You will not get reports or other information about any research that is done using your information.

There is a risk that someone could get access to your genetic information and identify you by name. The study doctors believe the risk of this happening is very small. However, the risk may increase in the

future as people find new ways of tracing information. For more information about how your genetic information is protected, ask your study doctor.

## 15. Conflict of Interest

This centre is receiving funds from the Ontario Institute for Cancer Research (OICR) to help offset the costs of conducting this research. OICR is a non-profit provincial organization. The researchers at this centre will not receive any direct benefit for conducting this study
The doctor treating you also may be the doctor in charge of this study.

If you would like additional information about the funding for this study, or about the role of the doctor in charge of this study, please speak to a member of the study team.

## 16. Where can I get more information?

A description of this registry will be available at www.OHCRN.ca. This website will not include information that can identify you. You can search this website at any time.

You may receive communication from OHCRN, such as updated screening policies, reports or newsletters, and to receive information about educational events. If you no longer want to receive these communications, let a member of the study team know.

You can talk to the study doctor about any questions or concerns you have about this study. Contact the study doctor:

Dr. Raymond Kim, MD, PhD raymond.kim@uhn.ca
437-244-3562

For questions about your rights while in this study, call the: Office of the Chair of the Ontario Cancer Research Ethics Board at: *416-673-6648 OR Toll free: 1-866-678-6427 ext. 6648*

## 17. Optional studies that you can choose to take part in

This part of the consent form is about optional studies that you can choose to take part in. Optional studies will either be directly related to the main registry study or will be for future research not related to the main registry study. You will receive no health benefits from participating in these optional studies.

By taking part in these optional studies, we hope the results will help other people with hereditary cancer in the future. The results will not be added to your medical records and you, or your study doctor, will not know the results.

Taking part in these optional studies is your choice. You can still take part in the main OHCRN registry even if you say “no” to the optional studies. There will be no loss of benefits for saying “no.” If you consent but cannot complete any of the optional studies for any reason, you can still take part in the main registry study (OHCRN).

**Optional secondary contact**

A clinical representative from OHCRN may contact your next of kin or secondary contact for updates to your health information if attempts to reach you have been unsuccessful. Ask your study doctor or a member of the study team if you would like to learn more about providing a secondary contact.

If you change your mind later, you can let the OHCRN team know that you no longer wish to provide a secondary contact.

**Optional release of contact information to existing approved cancer registries**

There are existing Ontario registries (specialized carrier clinics) which recruit specific patient populations and register their information into databases. This includes:

1. Cancer Care Ontario (Ontario Health) Breast Screening Program, which enrolls patients with a HCS breast cancer into high-risk breast screening with early mammography and breast MRI
2. The Ontario Familial Breast Cancer Registry (OFBCR), which maintains the population-based National Institute of Health-funded registry (run through Sinai Health System)
3. The Familial Gastrointestinal Cancer Registry (FGICR), which enrolls hereditary colon cancer, polyposis and Lynch syndrome patients (run through Sinai Health System)
4. The Familial Breast Cancer Research Unit, which enrolls *BRCA1/2* and *PALB2* carriers (run through Women's College Hospital)
5. The Pediatric Cancer Genetics Program, which enrolls children and families who are at an increased genetic risk for cancer (run through the Hospital for Sick Children)

The study team will identify whether you may be eligible for one of these existing cancer registries and will provide your name, contact information and carrier status, including genetic test results, to the registry study team. A member of the study team from the existing cancer registry will then contact you regarding enrollment into the registry.

If a new registry becomes available and is approved by OHCRN through OHCRN steering committee and set data-access approval process, we will provide your contact information to the registry study team, if that registry is applicable to you.

If you change your mind later, you can let the OHCRN team know that you no longer wish to release your contact information to existing cancer registries. However, it will not be possible to destroy any information that has already been shared with existing registries.

**Optional re-contact**

A member of the OHCRN study team may re-contact you about future research studies, clinical trials, surveys, and/or collection of biological specimens (i.e., blood sample). If you agree to re-contact, we may also directly provide your contact details, including your name, contact information and carrier status to the researcher leading the clinical trial or research study, without OHCRN contacting you first. If you agree to this, then a member of the trial or research study team will contact you to provide you with more information about the clinical trial or research study, including a consent form to sign, if you agree to participate.

Ask your study doctor or a member of the study team if you would like to learn more about being re-contacted.

If you change your mind later, you can let the OHCRN team know that you no longer wish to be re-contacted about future studies.

**Optional consent to allow collection of previously collected samples for future unknown research**

Researchers are trying to learn more about cancer and other health problems using blood and tissue samples from people who take part in clinical trials and research studies. By studying these samples, researchers hope to find new ways to prevent, detect, treat, or cure diseases. Storing samples for future studies is called "biobanking." A decentralized biobank means that we will not be collecting your samples to store in one location. Samples will remain at whatever location they were originally collected from, until they need to be used for research.

If you choose to take part in this optional study, access and use of previously collected archival tissue/biospecimens (i.e. tissue, blood, DNA samples) and associated clinical data may be provided to approved researchers as part of unknown future studies.

We will protect your privacy. The goal of decentralized biobanking is to make more research possible that may improve people's health. To access samples from the decentralized biobank, researchers must submit a specific research request to OHCRN. The request identifies who they are and what their planned research project is. Before getting the samples and data, the researchers must agree to keep the data private, only use it for their planned research project, and never use it to try to identify you. The research must also be reviewed and approved by a research ethics board, if needed.

Right now, we don't know what research may be done in the future using your blood and/or tissue. This means that:

- You will not be asked if you agree to take part in the future research studies.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your samples.

Unknown future research studies may include sequencing of all or part of your DNA. This is called genomic sequencing. Sequencing allows researchers to identify your genetic code. Changes in your genetic code may just be in your tumour tissue. These are called somatic changes. Changes may also be in your normal tissue and passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair colour are passed down. These are called germline changes. If only tumour tissue is sequenced we will not know if a genetic change in your tumour is also in your normal tissue. This is why sometimes both normal tissue and tumour tissue are sequenced. This helps researchers understand if a genetic change happened only in your cancer tissue or in your normal tissue as well.

Unknown future research studies that may access your previously obtained samples include, but are not limited to, using de-identified tissue for DNA/RNA extraction for sequencing for the purpose of discovering existing or novel underlying genetic basis of the disease, histological examination, imaging and/or immunohistochemistry.

If you are a First Nations or an Indigenous person who has contact with Elders, you may want to talk to them before you make a decision about this research study. Elders may have concerns about some research procedures including genetic testing.

It is unlikely that registering in OHCRN would result in any additional individualized unexpected findings. However, future unknown research, or knowledge gained from studying the clinical and genetic information from the registry may change the interpretation of some germline variants.

Finding these changes would not affect your involvement in the OHCRN registry but may affect your care. If this happens, your doctor would be notified of this information.

These samples would not be accessed or used immediately. The samples will remain in the location they are currently being stored.

**What is involved in this optional sample access?**
If you agree to take part, here is what will happen next:

1. Researchers whose projects have REB approval will request access to the available samples.
2. The OHCRN study team will facilitate the collection of the requested samples from the institution where the samples are being held.
3. Some of your genetic and health information may be placed in central databases for researchers to use. The databases will not include your name or contact information.

**What are the risks in this optional sample access?**

- Generally, hospitals will keep some of your tissue. This tissue may be used to help treat your cancer in the future. There is a small risk that when this tissue sample is submitted to the biobank for this optional sample access, your tissue could be used up.
- Your medical and genetic information is unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information in a database back to you. They could use that information in a way that could harm you. Researchers believe the chance that someone could access and misuse your information is very small. However, the risk may increase in the future as people find new ways of tracing information.

**How will information about me be kept private?**
Your privacy is very important to the study researchers. They will make every effort to protect it. Here are just a few of the steps they will take:

1. They will remove identifiers from your sample and information. They will replace them with a code number. There will be a master list linking the code numbers to names, but they will keep it separate from the samples and information.
2. Researchers who study your sample and information will not know who you are. They also must agree that they will not try to find out who you are.
3. Your personal information will not be given to anyone unless it is required by law.
4. If research results are published, your name and other personal information will not be used.

**What are the benefits to taking part in this optional sample access?**
You will not benefit from taking part and there are no associated costs to you. The researchers, using the samples from you and others, might make discoveries that could help people in the future. You will not receive any payment from these discoveries.

**What if I change my mind about this optional sample access?**
If you decide you no longer want your samples to be used, you can tell the study team, who will let the researchers know. Then, any sample that remains with the researcher will be destroyed or returned to

your study team. This will not apply to any samples or related health information that have already been given to or used by researchers.

**What if I have questions about this optional sample collection?**
If you have questions about the use of your samples for research, contact the study team.

## Agreement to take part in optional studies

Please circle your answer below to show if you would or would not like to take part in each optional study:

**Optional secondary contact**
I agree that my study doctor, or someone on the study team, may contact my next of kin or secondary contact for updates to my health information if attempts to contact me have not been successful.

YES NO

**Optional release of contact information to existing approved cancer registries**
I agree that my study doctor, or someone on the study team, may provide my contact information and genetic test results to an existing cancer registry, if applicable.

YES NO

**Optional re-contact**
I agree that my study doctor, or someone on the study team, may contact me in future, and/or provide my contact information to the research team for future research studies, and clinical trials, if applicable.

YES NO

**Optional consent to allow collection of previously collected samples for future unknown research**
I agree that my previously collected samples may be included in the decentralized biobank and used for unknown future research studies.

YES NO

**This is the end of the section about optional studies.**

_____

## My signature agreeing to take part in the study

I have read this consent form or had it read to me. I have discussed it with the study doctor and/or members of the study team and my questions have been answered. I will be able to download a signed and dated copy of this form from OHCRN portal. I agree to take part in the main study. I also agree to take part in any additional studies where I where I checked "yes".

| _____ | _____ | _____ |
|---|---|---|
| Signature of Participant | Printed Name | Date |
| _____ | _____ | _____ |
| Signature of Person Conducting the Consent Discussion, if applicable | Printed Name | Date |

**Complete the following declaration if you are completing consent on behalf of a minor and you are the parent or legal guardian:**

The consent form is addressed to the patient.

| _____ | _____ | _____ |
|---|---|---|
| Signature of Parent/Guardian | Printed Name | Date |
| _____ | _____ | _____ |
| Signature of Parent/Guardian | Printed Name | Date |

**Participant Assistance**

**Complete the following declaration only if the participant requires a substitute decision maker:**
This consent form is addressed to the patient. However, in the case the patient does not have the capacity to provide informed consent for themselves, the form is given to you as the substitute decision maker for whom informed consent will be obtained for participating in the registry.

| _____ | _____ | _____ |
|---|---|---|
| Signature of Substitute Decision Maker | Printed Name | Date |

_____
Relationship to Participant

**Complete the following declaration only if the participant is unable to read:**

- The informed consent form was accurately explained to, and apparently understood by, the participant, and,
- Informed consent was freely given by the participant.

| _____ | _____ | _____ |
|---|---|---|
| Signature of Impartial Witness | Printed Name | Date |

**Complete the following declaration only if the participant has limited proficiency in the language in which the consent form is written and interpretation was provided as follows:**

- The informed consent discussion was interpreted by an interpreter, and,
- A sight translation of this document was provided by the interpreter as directed by the research staff conducting the consent.

**Interpreter declaration and signature:** By signing the consent form I attest that I provided a faithful interpretation for the discussion that took place in my presence, and provided a sight translation of this document as directed by the research staff conducting the consent.

| _____ | _____ | _____ |
|---|---|---|
| Signature of Interpreter | Printed Name | Date |