Study Information and Informed Consent Form for
Prospective Data and Biospecimen Sharing

Research Network Title for Participants: *The Terry Fox Research Institute (TFRI) Marathon of Hope Cancer Centre Network Study*

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: *(Insert Study Number, "Insert Official Study Title")*

Trial Code: *(XX.XX)*

Study Doctor: Dr. _____
Sponsor: *(Sponsor name)*

If an REB approved French consent is not used at your institution remove this statement.
Le formulaire de consentement est disponible en français sur demande.

A 24-7 phone number is required for studies that include greater than minimal risk research procedures or interventions.
EMERGENCY contact number (24 hours/day 7 days/week): _____

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

Overview and Key Information

1. What am I being asked to do?

We are inviting you to take part in this research study because you have a cancer that is being studied in a program that is part of the national Marathon of Hope Cancer Centre Network. The purpose of the Marathon of Hope Cancer Centre Network is to use emerging technologies such as genomics, high-powered imaging and artificial intelligence to study cancer. This study does not provide you with any treatments. Instead, the study's main goal is to try to understand how we can give the right treatment, to the right patient, at the right time. This is known as precision medicine. This study is about uniting cancer research centers across Canada to share knowledge and resources to improve patient outcomes using precision medicine.

2. Taking part in this study is your choice.

You can choose to take part, or you can choose not to take part in this study. 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. 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 your study doctor (please see the contact information at the top of this page). 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?

This project will build a large data resource to help researchers across Canada and around the world understand why some cancers respond or do not respond to certain therapies, how to identify new therapies, and how precision medicine might affect economic or social issues. Approximately 15,000 participants will take part in this study across Canada.

Molecular information refers to the DNA, RNA and protein in your cells. These are codes that tell cells what their role is and how to work, like an instruction book. A string of DNA that has a certain function is called a gene. We "sequence" or read the code of a gene, much like letters in an alphabet help us read words. This project will read all of the code in your tumour and normal cells (approximately 6 billion letters). In cancer research, we are looking for errors in this code, called mutations. To help understand how these codes cause cancer and how to treat the cancer with precision medicine, we may also use your samples to look at other types of molecular changes and cell changes that occur in cancer. These studies may include looking at the interaction of the immune system with cancer cells.

Cancer is caused by a build-up of these errors in the DNA code of cells. This causes the cells to not behave as they normally do and divide uncontrollably. 5-10% of people with cancer were born with the first mutation or error (in some or all cells of their body) that most likely contributed to this process.

If you agree to take part in this study, your coded healthcare and genomic information will be shared as described below. Coded information does not include information that could directly identify you such as your name. Also, we may need to access or transfer your biospecimens (i.e., blood, urine, stools samples, tumor tissue) in order to validate results from these studies or use analytic tools or innovations that may not be available to all Network members. These biospecimens may have been collected as part of your clinical care or when you participated in a research study. If access is necessary, we will follow the storage, sharing, and destruction requirements that govern your biospecimens that are kept at your local site. Biospecimens would always be coded before leaving any local site and would be shared with Network members and their collaborators, which may include commercial collaborators.

Your information may be used for various research purposes, including projects that use genetic testing, mapping, whole genome sequencing (mapping the entire genome), treatment, prevention, and machine learning.[1] Technology advances may allow for new uses of the genomic information that are not known at this time. The Network has rules and restrictions that governs who can request your data and biospecimens and for what purpose. Scientists who are part of the Network will be certified and will be governed by agreements and a Data Access Committee. Before your information is shared with researchers outside of the Network, a Data Access Committee composed of doctors and scientists will need to approve requests for such access. Amongst the things they will ensure is that the research

[1] Machine learning is a type of Artificial Intelligence where computer programs learn from data automatically to see patterns that would be difficult or impossible for humans to observe on their own for example.

requesting access was approved by a Research Ethics Board[2] where required, and that it is scientifically reasonable.

4. What is the standard of care for this study?

If you do not wish to participate in this study, you will continue your cancer treatment with your oncologist as you normally would. Your treating oncologist can answer any questions you may have about standard of care.

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

There is no treatment provided as part of this study so there are no alternative treatments to consider. Your alternative is not to participate.

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

For this study we are inviting you to share data. Study team members will collect this information by reviewing your medical charts. By participating in this study, you are allowing the collection of this information. Some of the information collected will include: lifestyle factors; demographic information such as your age, date of birth, sex, race, ethnicity, and postal code; diagnosis history such as dates of diagnosis, imaging, staging and cancer pathology grading information; treatment information such as the types of chemotherapy, radiation therapy, or surgical procedures you have received, dates, details, reports, and outcomes of these treatments; laboratory tests that can include routine blood test results, diagnostic test results and the results of prior genetic testing and molecular data including whole genome sequence; scanned pathology slides and data about specimens derived from procedures; and patient reported outcomes data. These data will be used to better understand the results from the analyses of your biospecimens. You have already provided consent for your doctors to obtain biospecimens for these analyses. Here you are providing consent for sharing your data obtained from the analyses of your samples.

In some cases, your biospecimens may also be accessed, as described in the "Why is this study being done?" section above. If you agree, you may also be invited to complete questionnaires and participate in other engagement activities. If you decide to participate in any of the optional public engagement activities you may be invited to come to the clinic from time to time, attend events, or answer questions over the phone, via email, or online. These activities are optional, and you may stop at any time.

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

There will be no physical risks of harm associated with participating in this study. In this study, you are providing us with various types of personal information, including your genetic information.

[2] A Research Ethics Board is a body of researchers, community members, and others with specific expertise who review the ethical acceptability of research studies.

Participation in research may possibly involve some loss of privacy. For example, there may be a privacy breach (which could include unauthorized use, access, or disclosure of data).

To minimize risk, direct access to your medical records will be restricted to individuals who have signed an agreement to maintain confidentiality and will be limited to only certain study members. All other study members will see your coded data that does not include any personal identifiers.

Any biospecimens that you provide will usually be kept at your local study site. There are no plans to bank or store your biospecimens as part of this study. However, small amounts of your biospecimens might be held for validation studies. Validation studies help back-up research findings with additional tests.

We will provide your clinical, genetic and genomic data to researchers involved in studies about cancer, new therapies, treatment, and prevention. These studies will require approval by us, and a Research Ethics Board where applicable. We will require researchers to ensure they maintain privacy and security measures, including ensuring they keep any data secure from unauthorized access. They cannot attempt to identify you or otherwise contact you with respect to the research or any results. The researchers may be outside of Canada and may include industry research partners who may assist with activities like data analysis and visualization. Network members may receive research money from companies when they collaborate with them and share data. These researchers may use information from your results and/or their research along with other individuals contributing to this study in a pooled and non-personally identifiable manner for publication in association with research reports, scientific publications, therapies, treatment, and prevention. More information about these topics can be found in the Privacy & Confidentiality section of this form.

Benefits
You may or may not receive direct benefit from participating in this study. Data from your biospecimens, and from all individuals contributing to this study, will be pooled and used for research reports, presentations, interviews and scientific publications. It is hoped that there will be a benefit to future patients by using the information gained in this project to improve methods for testing new cancer treatments.

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

You will be told in a timely manner of any information that may be relevant to your willingness to stay in the study. You can decide to stop taking part in the study at any time. If you decide to stop, let your study doctor know as soon as possible. You can leave the study at any time for any reason without any consequences to your medical care.

You may withdraw your permission to use your personal health information for this study at any time by letting the doctor who invited you into this study know. However, this would also mean that you withdraw from the study. Your study data that was recorded before you withdrew will continue to be used to protect the integrity of the research, but no information will be collected or shared after you withdraw your permission.

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

The study doctor may take you off the study if the study is stopped by a regulator, Research Ethics Board (REB), or the Terry Fox Research Institute.

10. Incidental findings and return of results [Insert this section if investigators are planning on returning results according to local REB approved language and process]

[If investigators are planning to return results to patients, local REB approved language should be inserted here. Results must be returned with permission from participants. Please see the new TCPS Material Incidental Findings guidance: https://ethics.gc.ca/eng/incidental_findings.html. Examples of material incidental findings plans can also be found in Appendix A.

11. What are my responsibilities in this study?

This is a data and biospecimen sharing study that involves permission to share your data and biospecimens. There are no other additional responsibilities for participants. However, please tell your study doctor if you would like to withdraw from participation.

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

You will not have to pay to take part in this study and the study is ongoing. You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment. The research using your data and biospecimens may be shared with industry and other third parties for research partnerships that may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment. However, research partners may need to reimburse the Network for the costs associated with sharing data and biospecimens.

13. What happens if I am harmed because I took part in this study?

By signing this form, you do not give up any of your legal rights against the investigators, sponsor, or involved institutions for compensation, nor does this form relieve the investigators, sponsor, or involved institutions 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.

14. Who will see my medical information?

Federal and provincial privacy laws give safeguards for privacy, security, and authorized access to information. We will not give information that identifies you to anyone without your permission, except as required by law.

However, there is a risk of a privacy breach. A privacy breach is when information stored about you is accessed, it could be revealed inappropriately or accidentally, and the risk of someone identifying you may increase in the future as people find new ways of tracing information. Depending on the nature of the information, such a release could upset or embarrass you, or be misused. For example, it could be used to make it harder for you to get or keep a job or insurance. There are laws against this kind of misuse in Canada, but they may not give full protection, and laws in other countries may not be as strict as those in Canada, so when your information and biospecimens are sent to places outside of Canada for research, you may not be afforded the same rights. We believe the chance these things will happen is

very small, but we cannot make guarantees. Your privacy and the confidentiality of your data are very important to us, and we will make every effort to protect these as described below.

Study-related data and coding:

- All information gathered for use in the study is referred to as the 'study-related data'. This data may include your medical records, genetic and genomic information, completed questionnaires, etc. The study-related data will be transformed into datasets that can be analyzed. You will be assigned a unique code that will be used to track your study-related data. This unique code does not include any personal information that could identify you and will be used on all study-related data that leave the site unless otherwise specified in this form (this is referred to as 'coded data').
- Coded data (including genetic information) from this study may be shared with researchers and industry (commercial) partners from around the world. This sharing may include sharing of your data in future studies that are unknown at this time. The aim of these future studies is to benefit people by improving our understanding of health conditions like cancer. Sharing of coded study data with commercial partners may be tied with financial support for the study by the commercial partner. Your coded data may also be added to public databases (that are searchable), published, or presented at scientific meetings.
- Your data may be linked with national and/or provincial health administrative data to provide greater understanding of how people with a particular condition use the health care system. When data are linked, it may increase the risk of re-identification. However, all necessary steps will be taken to minimize this risk.

Who will know I participated?

- Your treating oncologists will be notified that you are taking part in this study.
- The study asks for you to share contact information for authorized family members if you are unable to receive study information in the future.
    - When you donate your data for genetic testing or research, you are not only sharing genetic information about yourself, but also about biological (blood) relatives who share your genes or DNA. Although sample ID methods remove information that may identify you, such as your name or personal health number, genetic information is unique to an individual (similar to a fingerprint). There is a risk that information gained from genomic research could eventually be linked to you. This could lead to loss of privacy and to possible future discrimination in employment or insurance, against you or your biological relatives. Every effort will be made to protect your privacy, the confidentiality of these results, and the privacy of any caregivers, family, or friends with whom you have authorized to share information. Please make sure you have told these authorized individuals that you will be sharing their information, and they agree to be contacted. If required by law, your medical information may also need to be given out. If this should happen, the study doctors and staff will do their best to make sure that any information that is shared will not directly identify you.

Genetic research will not include direct personal identifiers such as your name. 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. We may not advise you in all cases of

scientific advances or new information about therapies, treatments, and preventions. It is impossible to predict what sort of new information will come out of this sort of analysis. You should be aware that genetic information cannot be protected from disclosure by court order.

Unique personal identifier

The Marathon of Hope Cancer Centres Network is a long-term multi-site project. It is made up of many cancer programs currently running throughout the country. It is expected that patients will move to different provinces and may enroll in multiple programs. To minimize the amount of testing on patients in the Marathon of Hope Network we would like to create a unique personal identifier using your name and birthdate so that your identity can be connected to your coded data if necessary. These personal identifiers will be kept securely at each sequencing centre with no human contact to the list. Only a computer on a special network can look at this list. If you enroll in a new Marathon of Hope program, these computers will let the research staff know that you are already in the network and will allow the connection of your data from the old program to the new one.

The following section must be filled out for Ontario and Quebec. In addition, we will also record your [e.g., Ontario Health Insurance Plan (OHIP) number] for future linking of other information collected in this study with routinely –collected information about your health care found in health-related databases [e.g., OHIP physician claims database, Ontario Cancer Registry]. Authorized representatives of the following organizations will recover your [OHIP number] for data linkage purposes:

- [e.g., The institute for Clinical Evaluative Sciences (ICES) located at Sunnybrook Health Science Centre. ICES is a not-for-profit research institute and a prescribed entity under PHIPA (Personal Health Information Protection Act), and is authorized to collect health information in administrative healthcare databases.]

Your [OHIP number] will be recorded in a password protected database with restricted access, and securely stored at this centre. The study team at this centre will provide [describe their process here e.g., ICES with your OHIP number, along with your unique study code and study data. Authorized ICES personnel will then replace each OHIP number with a confidential code. This code is unique to each participant and common to ICES databases, which will allow the linkage of records belonging to the same individuals. ICES will then obtain information from their administrative health care databases and provide this information to the sponsor. The information will be de-identified before sending to the sponsor, so identifiers like your street address and phone number will not be included in the information.]

Your study-related data will be reviewed by the sponsor of this study (the organization legally responsible for the management of the study), or their representatives at **your site***. The **** Research Ethics Board or regulatory authorities like Health Canada and auditors may also look at your study-related data or biospecimens for the purpose of overseeing the conduct of the study. Your signed consent form will be included in your study-related data, and in any electronic medical record(s). Your healthcare team will also be alerted that you are on a study. By signing this form you are authorizing such access.

How long will study –related data be kept?

Your study records including confidential information about you collected during the study will be kept at a secure location (STATE LOCATION, DATA WORKING GROUP) indefinitely (forever). Remaining

genomic data and your coded clinical data will also be kept indefinitely. Biospecimens that may be accessed as part of this study will be kept, preserved, stored, and disposed of according to the rules and guidelines that govern them at your local site.

15. Conflict of Interest

This study is being sponsored by the Terry Fox Research Institute and its funding partners, which include your XX Institution and government sources, and may include research funding agencies and commercial entities. Your XX institution may have partnered with other co-funders as well. This means that XX institution has received funding from these sponsors to do the study. However, none of the study doctors or staff will receive any personal payments.

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 the study staff or to your Research Ethics Board.

16. Where can I get more information?

A description of this project will be available on *(insert full web address)*. This website will not include information that can identify you. You can search this website at any time.

Aggregated study results (the combined results of many people) will be communicated directly to participants using a website that will be updated on a regular basis (*insert full web address*).

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

(Insert name of study doctor[s])	*(Insert telephone number, and email address if appropriate)*
Name	Telephone

For privacy related questions or questions about your rights while in this study, call the:

(insert REB questions line here)	Telephone

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

This part of the consent form is about optional activities that you can choose to take part in. Optional activities will either be directly related to the main study or will be for future research not related to the main study. These optional studies may not benefit your health.

Patient engagement activities

- You may be invited to participate in questionnaires and other engagement activities. These will have their own consent forms and you do not have to answer any question that makes you feel uncomfortable. Since these are only for research purposes, your responses will not be reviewed by the study doctor. If you have any health or study-related concerns, please talk with the study team directly. These engagement activities will be described in detail in optional consent forms that will be provided to you when you are invited to participate.

Optional engagement activities:

- ☐ Yes, I would like to be notified about opportunities to complete questionnaires and participate in other engagement activities
- ☐ No, I do not want to be notified about opportunities to complete questionnaires and participate in other engagement activities
  Please initial here: _____

Re-contact: A new consent form will be necessary for the use of your data in other research that falls outside of the research goals this consent form. May we re-contact you in the future to tell you about additional research opportunities?

- ☐ Yes, you may re-contact me about additional research opportunities
- ☐ No, you may not re-contact me about additional research opportunities
  Please initial here: _____

If you answered yes to one or more of the above statements, it is important for you to keep the study coordinator informed about any changes to your contact information.

In the event that the study coordinator is not able to contact you directly regarding the research study or future information, you may designate a proxy contact here:

Full name: _____

Relationship to you: _____

Address: _____

Phone number: _____

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 my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the main study. I also agree to take part in any additional activities where I indicated "yes".

My signature on this consent form means:

- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive.
- I authorize access to my medical records, biospecimens, and genetic and genomic information, as well as my study-related data as described in this consent form.
- I am not waiving any of my legal rights by signing this consent form.
- I hereby consent to participate in the study as described in this consent form.

[If Investigators plan to return material incidental findings to participants, the participant must be given the opportunity to indicate if they wish to be made aware of this information on the last page of this consent form. A checkbox should be added to indicate willingness to receive results-see appendix A.]

_____	_____	_____
Signature of Participant	Printed Name	Date
_____	_____	_____
Signature of Person Conducting the Consent Discussion	Printed Name	Date

Participant Assistance

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

Appendix A. Sample material incidental findings sections from REB approved Canadian consent forms are provided below for your reference.

Example 1. Study title: Personalized Oncogenomics (POG) Program of British Columbia: Utilization of Genomic Analysis to Better Understand Tumour Heterogeneity and Evolution

BCCA Principal Investigator: **Dr Janessa Laskin**, Medical Oncology
BC Cancer Agency, Vancouver Centre
(604) 877 6000 local 672617

Co-Investigator: **Dr. Marco Marra**
BCCA Genome Sciences Centre
(604) 675 8162

Risks of Hereditary Genetic Research

Tumor-normal sequencing is available to help guide your cancer management. Before you consent to it, you should understand the following things.

- Cancer is caused by the accumulation of errors in the DNA known as mutations. This causes the cells to behave abnormally and divide uncontrollably. 5-10% of people with cancer were born with the first mutation (in some or all cells of their body) that most likely contributed to this process. Identification of a mutation that causes cancer that a person was born with, may indicate that there is a higher risk for future cancers, and that blood-related family members may also be at risk for having inherited the same predisposition (which means susceptibility or tendency) to cancer.
- Most of the time a cancer predisposition will have already been recognised through a family history of cancer at a young age or multiple cases of cancer, however, in some cases there may not be an obvious family history.
- If we identify one of these mutations or gene abnormalities that is known to be associated with inheriting a risk to develop cancer, we call this a "secondary finding". **Secondary findings** are those that relate to cancer susceptibility genes. If we discover one of these abnormalities in your inherited genes this may be something that affects the rest of your blood-related family. Identification of a cancer predisposing mutation in a healthy individual does not always mean that they are guaranteed to get cancer, but can indicate that there is a significantly higher chance of cancer development for which cancer screening and cancer risk-reduction strategies may or may not be available.
- We cannot do the study without examining these aspects of your DNA and if we find something we are obligated to inform you. **Therefore, if you are not willing to accept the risk of discovering a cancer-related inherited (germ line) finding in you, and therefore possibly in your family, then you should not participate in this study.**

- In addition to those that may be related to your current cancer, sometimes if we look for cancer susceptibility genes we might identify gene mutation(s) that may not be related to your current cancer. The discovery of unexpected genetic results is sometimes called **incidental findings**. This is not something the researchers are looking for or will search for, this would be something noted only incidentally. These findings may indicate an increased risk of developing certain non-cancer medical conditions. As these findings are not related to cancer the study allows you to opt-in or opt- out of receiving information on non-cancer related inherited genomic findings. There is a check box at the end of the consent form and you should indicate your wish to receive or not receive incidental findings if there are any identified.
- The knowledge that one has a disease-related gene might alter one's decision to have a child or other life-style decisions.
- *If the research data requires clinical validation of an unexpected finding, such as an inherited genetic abnormality, this will be coordinated with your supervising oncologist to ensure that you receive the proper medical genetic counselling and care. This will address issues or concerns related to hereditary cancer risk and inform you of the cancer risk management options available for this condition. Knowing your or family's risk may generate recommendations regarding cancer prevention and treatment.*
- When you donate your blood or tissue for genetic testing or research, you are sharing genetic information, not only about yourself, but also about biological (blood) relatives who share your genes or DNA. Although sample ID methods remove information that may identify you, such as your name or personal health number, genetic information is unique to an individual (similar to a fingerprint). There is a risk that information gained from genetic research could eventually be linked to you. This could lead to loss of privacy and to possible future discrimination in employment or insurance, against you or your biological relatives. Every effort will be made to protect your privacy and the confidentiality of these results and they will not include your personal identification such as your name. 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. We may not advise you in all cases of scientific advances or new information about therapies, treatments, and preventions. As it is impossible to predict what sort of new information will come out of this sort of analysis, it is hard to predict the situations in which we may or may not be able to inform you of new findings. If the new information is not felt to be clinically relevant or validated then it is not likely to be passed along to you. In addition, after the study closes, or if you should be lost to follow up, or pass away we would not be able to keep you updated. You should be aware that genetic information cannot be protected from disclosure by court order.

If there are any specific genetic changes found in your cancer sample that may be able to be used as a target for drug therapy, you may have an opportunity to try a specific drug but it may or may not have benefit to you. It is also possible that a drug is identified but it is not approved for use by Health Canada and/or available in Canada. This means that there might be a drug that is identified but not available and this can be frustrating and disappointing. Whenever possible your oncologist will work with you to find a solution to that problem, but it is possible that we will not be able to get the drug(s) identified by this study. In that situation there may be other chemotherapy options for you and your oncologist will discuss this with you.

The formal reports about the results of these genomic tests will not be put into your medical records. However, it is highly likely that your oncologist will enter notes into your records regarding your consent and enrolment in this study and any specific abnormalities that were found, particularly if the findings lead to a discussion about treatment.

The data generated from this study is for research purposes. Given the exploratory nature of this trial and the need for expert interpretation, subjects will not have access to the research data. If specifically requested by you and if you can provide the appropriate computer equipment, then you may have access to the "rawest" form of the genomic data we can provide; this will not include any interpretation of such data. If you chose to analyze this raw data on your own (or with another institution) it will **not** be possible to for us to explain, discuss or re-analyze any findings or discrepancies in findings or interpretations. This means that if you do ask for your raw data and have someone else do an interpretation you may end up with different results and there may not be a clear explanation as to why this is. Although the raw data is immutable (it's not something that changes) it is possible that a different computational tool might analyze it differently and the findings may not be reconcilable; this could lead to confusion and frustration.

As this is a very new field of research and there are questions about issues such as having reports in the chart, returning incidental findings to patients, and protecting confidentiality, the POG program has formed a POG Ethics group (consisting of clinicians, scientists, genetic counselors and ethicists) to address these sorts of questions and other issues that come up as there are no clear guidelines for how to deal with such new situations.

This is a research study and as such validation tests that are clinically accredited are not a standard part of the study. It may be that the genetic analysis identifies a finding that cannot be validated or there is discordance between the research data and a clinically validated test. If this does occur and a potential treatment is based on this abnormality, your treating oncologist will discuss the risks of making decisions based on an unvalidated research finding.

The indication of consent to receive findings at the end of the consent form

I am aware of the hereditary genetic tests that are part of this study and one of the risks or participating is that I will be informed if a cancer-related susceptibility abnormality is found in my genome. I understand that the study is not focused on finding abnormalities related to possibly inherited diseases that are not related to cancer however it is possible that such an "incidental finding" may be discovered and if that does occur I would like to be informed of this finding.

Yes _____ No_____ (please indicate your choice)

Example 2. Study Title: Comprehensive Molecular Characterization of Advanced Pancreatic Ductal Adenocarcinomas (PDAC) for Better Treatment Selection: A Prospective Study

Study Number: COMPASS-001 – MUHC Cohort
Investigator/Study Doctor: Dr. George Zogopoulos

Blood and Tumor Samples for Gene Testing:
Blood and tumor samples (biopsy) will undergo genetic testing called "sequencing" to look for mutations in their genes. Blood samples will also undergo biomarker testing which will look at other substances such as proteins that may be important indicators for advanced pancreatic ductal adenocarcinomas or response to treatment. These samples will also be transferred to the Ontario Institute for Cancer Research (OICR), Mount Sinai Hospital (Toronto) or any third parties which they may be in contract with, for whole genome sequencing. Based on the testing required, your samples may also be transferred to another participating site involved in this research study. The current participating sites include Princess Margaret Cancer Centre, Kingston General Hospital, McGill University Health Centre, Nova Scotia Cancer Centre, and Centre Hospitalier de l'Université de Montreal.
The results of some of the genes sequenced (for example, *BRCA1*, *BRCA2,* and *PALB2*) will be given to the study doctor who may share the information with you, if you choose to receive it. If you choose to learn the results of the testing, the study doctor will refer you to a genetic counselor who will discuss the specific tests in more detail and the implications of the results with you. You will be asked to make your decision at the end of this consent form. In the event that you are not able to receive this information, you can consent for this information to be shared with your next of kin. You can consent to this at the end of the form.

Tumor Samples for Xenografting
A part of your tumor sample may be used to make living models of human pancreatic cancer (i.e. growing the tumor tissue in mice) for gene Testing to look for gene mutations related to treatment sensitivity and resistance.

Use of Samples for Future Research:
You will be asked if you agree to allow the researchers to perform additional tests on your samples in the future as new biomarkers are discovered. This is optional. You will be asked to make your decision on a separate optional consent. If you agree, you will not be contacted for your specific permission to do most of these future research tests.

Genetic Testing:
When you donate your blood or tissue for genetic testing or research, you are sharing genetic information, not only about yourself, but also about biological (blood) relatives who share your genes.

There is a risk that information gained from genetic research could eventually be linked to you. This potential re-identification of the information (e.g., to an employer or insurer) could lead to loss of

privacy and to possible future discrimination in employment or insurance, against you or your biological relatives.

Benefits:

You may not receive any direct benefit from being in this study.

However, the results of some of the genes sequenced (for example, *BRCA1*, *BRCA2*, and *PALB2*) will be given to the study doctor who may share the information with you, if you choose to receive it. If you choose to learn the results of the testing, the study doctor will refer you to a genetic counselor who will discuss the specific tests in more detail and the implications of the results with you. You will be asked to make your decision at the end of this consent form.

We may also discover information by testing your blood and tumour that may help your cancer doctors with your cancer treatment in the future (such as future chemotherapy choices), but the study doctor will only give this information to your cancer doctor if you provide us with permission. You will be asked to make your decision at the end of this consent form.

The indication of consent to receive findings at the end of the consent form

Information learned from this study may also help other people with pancreatic cancer in the future.

Please make your choices prior to signing:

Results of Gene Testing:

☐ Yes, I wish to receive the results of the genetic sequencing that may increase my risk and/or my family's risk for cancer or other diseases, if they are found.

Should circumstances arise such that I am unable to receive this information, you have my consent to contact a family member. (Please designate a family member to receive information about genetic changes, if found. If you do not wish to provide a contact name, please leave this item blank.)

_____ _____ _____

Delegate name (Print Name) Relationship Phone Number

(Prefer a blood relative)

☐ No, I do not wish to receive the results of the genetic sequencing that may increase my risk and/or my family's risk for cancer or other disease, if they are found.