CancerCare Manitoba
ActionCancerManitoba

THE MANITOBA TOMORROW PROJECT

Participant Information Booklet

In Partnership With:

The *Manitoba Tomorrow Project* is supported by CancerCare Manitoba, and the Canadian Partnership for Tomorrow's Health, an initiative of the Canadian Partnership Against Cancer. The *Manitoba Tomorrow Project* is currently based at CancerCare Manitoba.

CANADIAN PARTNERSHIP AGAINST CANCER
PARTENARIAT CANADIEN CONTRE LE CANCER

CanPath
Canadian Partnership for Tomorrow's Health

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Participant Initials: _______

PARTICIPANT INFORMATION BOOKLET

Title of Study: Manitoba Tomorrow Project

Principal Investigator(s): Dr. Donna Turner, Provincial Director of Population Oncology, CancerCare Manitoba & Dr. Spencer Gibson, Interim Provincial Director of Research, CancerCare Manitoba

Project Coordinator(s): Nikita Lysenko MSc, Epidemiology Research Coordinator, CancerCare Manitoba

Sponsor(s): CancerCare Manitoba (CCMB), Canadian Partnership Against Cancer (CPAC)

We would like to invite you to participate in a long-term health study called the *Manitoba Tomorrow Project*. This booklet explains what the project is about. Please take your time to read it carefully, and take as much time as you need to decide if you want to participate. Feel free to talk about it with your friends, family or (if applicable) your doctor before you make your decision. **Participation is voluntary**. This booklet may contain words that you do not understand. Please ask the project staff to explain any words or information that you do not clearly understand.

This work is being financially supported by the Canadian Partnership Against Cancer, with in-kind support from CancerCare Manitoba.

If you have any questions, don't hesitate to contact us:

Call us at:	1-855-588-0658
Visit our website at :	www.manitobatomorrowproject.ca
Send us an e-mail at:	CCMBTomorrow@cancercare.mb.ca

Write a letter to:
The Manitoba Tomorrow Project
CancerCare Manitoba
675 McDermot Avenue
Winnipeg, Manitoba R3E 0V9

WHAT IS THE MANITOBA TOMORROW PROJECT?

The *Manitoba Tomorrow Project* is a longitudinal population cohort. This means that the group of people that participate in the project (the cohort) are followed over an extended period of time. In this project, it will be for up to 50 years and will involve regular contact with you. This project is part of a larger Canada-wide initiative called the Canadian Partnership for Tomorrow's Health (CanPath). CanPath is the largest health research project in Canada, and has enrolled over 330,000 Canadians across the country. The purpose of CanPath is to better understand the causes of cancer and other chronic diseases, such as heart disease, stroke, multiple sclerosis, diabetes, Alzheimer's disease, and other health conditions. Researchers will study how different factors -like environment, genes, illness, diet, exercise and lifestyle- interact with one another to influence risk for cancer and other chronic health conditions. Results from these studies will help us over time to better understand why some people develop cancer and other chronic diseases while others do not.

Six regional cohorts (BC Generations Project, Alberta's Tomorrow Project, The *Manitoba Tomorrow Project*, Ontario Health Study, CARTaGENE, and Atlantic PATH) are currently participating in CanPath, working together with common goals. Manitoba is the only province that is currently accepting new volunteers, and aims to recruit at least 10,000 participants to the *Manitoba Tomorrow Project*.

Pour recevoir ce livret d'information en français, veuillez communiquer avec:
Nikita Lysenko, Coordinateur d'étude
Téléphone: 1-855-588-0658
Courriel: CCMBTomorrow@cancercare.mb.ca

WHO CAN TAKE PART?

You may choose to join this project if you:

- Are between 30-74 years of age
- Live in Manitoba

WHAT WILL I BE ASKED TO DO IF I TAKE PART?

If you volunteer to participate in this project, you will be asked to do the following:

1) **Review the study information in this booklet very thoroughly.**

2) **Complete a questionnaire about health and lifestyle.**
   This questionnaire will take about 45 minutes to complete. All of the questions are designed to help understand more about the different factors that may be associated with risks for cancer and other health conditions. You have the option not to answer any questions that you are not comfortable with.

3) **(OPTIONAL) Visit our study center sometime in the future, to:**

   Have some simple body measurements taken-
   A trained staff member will take some or all of the following measurements:
   - Blood pressure and heart rate
   - Waist and hip circumference
   - Standing and sitting height
   - Weight and body composition

   You can choose to not have any or all of the measurements if you do not feel comfortable being measured. If you so choose, we can share the results from these measurements with you. If we find abnormal results from these tests, for example if your blood pressure is very high, we are obliged to share these results with you. It is important for you to know that this assessment does not amount to a medical checkup by a qualified physician.

   Donate a small amount of blood and urine-
   Blood is a source of genetic information (DNA). Changes in DNA can give rise to diseases, but it is not always clear why or how these changes occur. Levels of hormones, vitamins and other environmental factors can be measured in blood and urine. Combining this information with information about your health and lifestyle from the questionnaire will help researchers to understand more about what causes cancer and other chronic diseases. On the day of your appointment, a trained staff member will ask you some questions to determine if it is safe to take a blood sample from you. If

it is, and you agree, he/she will take about 37mL (2-3 tablespoons) of blood from a vein in your arm. During your visit, you will be directed to a washroom and asked to provide about 20mL (1-2 tablespoons) of urine as well. You can eat and drink normally on the day of your appointment.

The study visit takes approximately 45 minutes to complete. You can indicate your interest in this optional visit on page 3 of the 'some personal information & consent form' document in your study package. After we receive your study package back in the mail, we will telephone you to arrange a time and date for the visit.

4) **Give permission to have your biological samples and information stored.**
Your biological samples and information will be stored for future use in health research studies. Your biological samples and information will be coded (i.e. your name will be replaced by a code) and stored in a highly secure, protected site at the Manitoba Tumor Bank of CancerCare Manitoba; Your biological samples will be placed into tubes and frozen at -80°C in freezers, while your information (records of the biological samples, questionnaire responses and physical measures results) will be stored electronically on encrypted and password protected devices, both inside locked, restricted access facilities.
Your name and other personal identifying information (contact information, health card number) will be stored in a separate electronic database (a 'key file') from the biological samples and information described above. This key file will be the only record that contains your identity, and thus the only link between your unique code and your personal identifiers. Only authorized personnel from the Manitoba Tumor Bank and *Manitoba Tomorrow Project* will have access to your personal identifying information, under controlled conditions.

5) **Agree to be contacted in the future for follow up research.**
The *Manitoba Tomorrow Project* is a long-term health initiative. This just means that the people that participate are followed for up to 50 years with regular contact. Regular contact allows researchers to follow how health changes over time.

We might contact you in the future to:

- Ask more questions
- Ask you to donate more biological samples

- Ask you to participate in other research studies
- Keep you informed about the progress of the study through regular newsletters

Your participation throughout the duration of the project is completely voluntary.

6) **Give permission to access your past, present and future health records**
We will ask you to provide us with your Personal Health Identification Number (PHIN; found on your Manitoba health card), so that we can access your past, present and future health information, and link it with the biological samples and information you provide to the project. For example, information could include test results, medical procedures, x-rays, and medicines you take. Databases that may be used by the project include:

Manitoba Cancer Registry:
Located at the CancerCare Manitoba in Winnipeg, the Cancer Registry keeps a confidential record of all cancer cases diagnosed in Manitoba, along with detailed information about the diagnosis, like when the cancer was diagnosed, the type of cancer, stage of cancer, and the type of treatment received. It is important that the *Manitoba Tomorrow Project* keeps track of all project participants who may develop cancer, or die of cancer. Therefore, the Project will apply to check the Manitoba Cancer Registry from time to time to see if any participants are listed.

Manitoba Health Insurance Registry:
This registry keeps confidential information on the health services used by Manitoba residents. As the purpose of the *Manitoba Tomorrow Project* is to learn more about the causes of cancer and other health conditions, information about types of diseases that develop, type of health care services people need and use, and how often health care services are used, is critically important to know. The *Manitoba Tomorrow Project* will apply to access specific information from the Manitoba Health Insurance Registry. If Manitoba Health accepts the request, the information will be confidentially released to the *Manitoba Tomorrow Project*. Mostly this information will be about reasons for visits to the doctor and/or the hospital.

Other databases that the *Manitoba Tomorrow Project* may want to access include, but are not limited to, the Federal Vital Statistics database (records of deaths) and pharmacy databases (records of medicine prescriptions). The *Manitoba Tomorrow*

Project will **NOT** request or obtain any notes or medical records from your family physician or any other physician you may get referred to. The information collected from all of these databases (known as administrative data) will mostly be analyzed to look at patterns and trends in large groups of people.

WHAT HAPPENS TO THE BIOLOGICAL SAMPLES AND INFORMATION I PROVIDE TO THE PROJECT?

When we receive your biological samples and information we will remove the personal identifying information (your name, address, and health card number) from them and replace it with a unique code. Your coded biological samples and information will be stored in highly secure, protected sites at the Health Sciences Center in Winnipeg, including at the Manitoba Tumor Bank of CancerCare Manitoba. Your biological samples will be placed into tubes and frozen at -80°C in freezers, while your information will be stored electronically, inside locked, restricted access facilities. Only authorized staff from the Manitoba Tumor Bank and the *Manitoba Tomorrow Project* will have access, under controlled conditions.

A small portion of your blood sample may be analyzed at a lab right after your study center visit, by performing a test called a Complete Blood Count (CBC). A health professional associated with the *Manitoba Tomorrow Project* will contact you by telephone to inform you if the analysis of your CBC reveals very serious results that may require additional tests. The rest of your biological samples will be frozen so that researchers can use some of it in the future.

WHO WILL HAVE ACCESS TO MY PERSONAL IDENTIFYING INFORMATION?

Your personal identifying information (name, address, and health card number) will only be accessible by authorized personnel from the *Manitoba Tomorrow Project* under controlled conditions. This access will be only for the purposes of contacting you for additional information.

Rarely, your personal identifying information may need to be checked for quality control purposes. Quality control procedures are put in place to ensure that the *Manitoba Tomorrow Project* collects and uses information accurately. Quality control inspections could be carried out by Health Canada or the University of Manitoba Research Ethics Board. Any disclosure of your personal identifying information will be in compliance with the Personal Health Information Act (PHIA) of Manitoba.

WHO WILL HAVE ACCESS TO MY BIOLOGICAL SAMPLES AND INFORMATION, AND HOW WILL YOU KEEP MY IDENTITY CONFIDENTIAL?

Other than authorized personnel who will have access under controlled conditions, researchers who study cancer and other chronic diseases may apply to access the biological samples and information collected in the *Manitoba Tomorrow Project* to carry out research. Your privacy is very important to us, and we will make every effort to protect it. Replacing your personal information with a unique code will allow us to share biological samples and information with researchers while keeping your identity confidential. Researchers will only be given access to coded information that cannot be used to identify you or anyone else in the project. All researchers who apply to access the *Manitoba Tomorrow Project* data for their research projects will be required to have their project plans reviewed and approved by a Research Ethics Board. Research Ethics Boards look after research projects that involve humans (including biological samples and information collected from humans) for the purpose of research, to ensure that the proposed research will be carried out according to the highest ethical and scientific standards.

If research is approved, the researcher then must submit an application to the *Manitoba Tomorrow Project*. If the application is approved, the researcher may be given biological samples and information. Researchers will also be required to sign an access agreement that says they can only use the data for the approved project, and that they will not try and find out who you are.

In the future, a portion of the *Manitoba Tomorrow Project* data may be combined with data donated by people taking part in the other regional cohorts of CanPath (BC Generations Project, Alberta's Tomorrow Project, Ontario Health Study, CARTaGENE, and Atlantic PATH), and will be managed by CanPath. Access to researchers will be managed in a way similar to that described for the *Manitoba Tomorrow Project* in Manitoba.

If a portion of the *Manitoba Tomorrow Project* data is transferred out of Manitoba to CanPath, strict conditions for transfer will be in place. Administrators of the data sent to CanPath will only be given access to coded information that cannot be used to identify you or anyone else in the project.

Even though every effort will be made to keep your personal information confidential – in compliance with the Personal Health Information Act (PHIA) of Manitoba – absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law.

WHO WILL NOT HAVE ACCESS TO MY BIOLOGICAL SAMPLES AND INFORMATION?

Your family members, friends, employers and insurance companies will not be able to access any information about you that has been collected from the *Manitoba Tomorrow Project*. While absolute confidentiality cannot be guaranteed, the *Manitoba Tomorrow Project* will make every effort to keep your information confidential.

WILL I RECEIVE RESULTS FROM RESEARCH DONE USING MY BIOLOGICAL SAMPLES AND INFORMATION?

If analysis of your blood sample right after your study centre visit reveals very serious results that may require additional tests, a health professional associated with the *Manitoba Tomorrow Project* will contact you by telephone to confidentially inform you, using the contact information you provide when making an appointment.

Researchers who use *Manitoba Tomorrow Project* biological samples and information in the future might discover something unexpected that could significantly affect a participant's health (known as an 'incidental research finding'). A researcher could uncover something that could be life-threatening, or reveal a serious condition that could be treated or prevented. In the event of this occurring, the Research Ethics Board, the researcher and the *Manitoba Tomorrow Project* will work together on a case-by-case basis to reach a decision about whether or not the incidental research finding should be communicated to the participant.

Unless researchers uncover incidental findings as described above, you will not receive any individual results if your biological samples and information are used by researchers in the future.

FOR HOW LONG WILL MY BIOLOGICAL SAMPLES AND INFORMATION BE STORED?

The project will store your biological samples and information for up to 50 years; up until April 1st, 2068. All biological samples and information will be destroyed at the end of the project, unless otherwise specified by a Research Ethics Board or equivalent authority in place at that time.

WHAT HAPPENS TO MY BIOLOGICAL SAMPLES AND INFORMATION AFTER I DIE?

Biological samples and information collected by the *Manitoba Tomorrow Project* may be used for research purposes after you pass away or are unable to make decisions on your own, unless you tell us differently while you are still alive.

HOW MANY PEOPLE WILL BE IN THIS PROJECT?

For the full project, at least 10,000 participants will be recruited from throughout the province of Manitoba. Over 330,000 participants have already been recruited from other provinces across Canada.

WHAT DO I DO IF I WANT TO TAKE PART IN THE PROJECT?

Simply contact us: Visit our website at www.manitobatomorrowproject.ca and fill out the contact form; call us toll-free at 1-855-588-0658; or direct at 1-204-787-8890 Monday-Friday, 9:00am – 5:00pm Central Standard Time; or send us an e-mail at CCMBTomorrow@cancercare.mb.ca.

IF I JOIN THE PROJECT NOW, CAN I WITHDRAW LATER?

Your decision to take part in this project is totally voluntary. You may withdraw from the project at any time, and you do not have to say why. If you choose to withdraw, simply contact us and let us know in what way you would like to withdraw. There are three 'levels' of withdrawal:

No further contact: The *Manitoba Tomorrow Project* will no longer contact you, or ask you to participate in any follow-up activities, like completing follow-up questionnaires. We will still have your permission to store and use the biological samples and information you have provided, and to access information in your health records.

No further access: The *Manitoba Tomorrow Project* will no longer contact you, or ask you to participate in any follow-up activities. We will still have your permission to store and use the biological samples and information you have provided, but we will **NOT** access any further information about you from your health records in the future, from the time of your withdrawal onwards.

No further use: The *Manitoba Tomorrow Project* will no longer contact you, or ask you to participate in any follow-up activities. We will not access any more information about you, the information you provided us will be removed from our databases, the information we accessed from your health records will be removed from our databases, and your biological samples will be destroyed. However, we **CANNOT** remove or destroy biological samples and information that have already been granted to approved researchers before your decision to withdraw.

WHERE CAN I FIND INFORMATION ABOUT MY RIGHTS AS A PARTICIPANT?

For questions about your rights as a participant in health research, you may contact The University of Manitoba, Bannatyne Campus Research Ethics Board Office at (204) 789-3389. By participating in this project, you do not waive any rights afforded to participants in research studies. Do **NOT** sign this consent form unless you have had a chance to ask all questions you might have, and have received satisfactory answers to all of those questions.

Your rights to privacy are legally protected and guaranteed by provincial laws to ensure that your privacy is respected. Further details about these laws are available on the web site of the Manitoba Ombudsman, https://www.ombudsman.mb.ca/.

WILL I BE PAID TO PARTICIPATE IN THIS PROJECT?

You will not receive any payment for participating in this project. Should you experience expenses related to the project (i.e., loss of wages/travel) you will not be compensated. Parking charges for your visit to the CancerCare Manitoba study center will be reimbursed up to a maximum of 2 hours.

WILL THE PROJECT LEAD TO ANY COMMERCIALIZATION?

Research using your biological samples and information could in the future lead to commercialization of a medical test or product- some researchers may also benefit financially from any future commercialization. If a commercial product is developed as a result of research conducted through accessing your biological samples and information, you will not receive any personal financial benefit.

WHAT ARE THE RISKS INVOLVED?

There are no major physical health risks involved in taking part in this project. Some of the questions in the questionnaire may be awkward or upsetting to you. There are the usual risks related to blood collection performed by a qualified health professional, which can sometimes cause bruising, pain, or rarely, fainting. There is also a small risk of infection associated with blood draws. You are entitled to the benefits available under your provincial health plan or First Nations and Inuit Health Branch Non-Insured Health Benefits Plan (if applicable) as well as those provided through additional private health insurance (if applicable).

Disclosure of genetic information could potentially result in discrimination toward you or your biological relatives by employers or insurance providers. However, the chance of your genetic information being released is extremely small, and every precaution will be taken to protect your privacy and the confidentiality of the information you provide.

WHAT ARE THE BENEFITS FOR ME AND/OR FOR SOCIETY?

We do not anticipate any direct benefits to you for participating. Your participation in the *Manitoba Tomorrow Project* may contribute to a better understanding of the causes of cancer and other chronic diseases, and what influences health and illnesses for many Manitobans. Findings from this research may help us find ways to prevent cancer and other chronic diseases. These findings will mostly benefit future generations of Canadians.

IF I HAVE ANY QUESTIONS OR PROBLEMS, WHO DO I CONTACT?

If you have any questions, concerns or complaints about any aspects of the project:

Call us at:	1-855-588-0658
Send us an e-mail:	CCMBTomorrow@cancercare.mb.ca
Write a letter to:	*The Manitoba Tomorrow Project* CCMB – MacCharles Site 675 McDermot Avenue Winnipeg, Manitoba R3E 0V9

For questions about your rights as a research participant or about ethical issues related to this project, you may contact someone who is not directly involved in the project. That person is:

The University of Manitoba
Health Research Ethics Board (HREB)
Research Ethics Boards Coordinator
Telephone Number: (204) 789-3389

Do not sign this form unless you have had a chance to ask questions and have received satisfactory answers to all your questions.

Thank you for considering joining the Manitoba Tomorrow Project!