The following is applicable to those residing in all provinces except Alberta. Please see document applicable to Alberta below.

CANRISK Questionnaire Informed Consent & Participant Agreement Form

Version 5.0 January 7, 2021

RESEARCH PROJECT AND TITLE: Prevention of Type 2 Diabetes using a Digital Wellness Coaching Intervention: The Canadian Diabetes Prevention Program

PROTOCOL NUMBER: Canadian Diabetes Prevention Program (CDPP)

PRIMARY INVESTIGATOR: Harpreet Bajaj MD, MPH, FACE

SPONSOR: **LMC Health Care**

TELEPHONE: 905-595-0560

Study Support Representative

Brad Lang, Project Manager
(416) 559-4665
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Vaughan, ON L4K 4M2

LMC (Brampton)
2979 Bovaird Drive East
Brampton, ON L6S 0C6

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140 Oxford Street East, Suite 410
London, Ontario N6A 5R9

LMC (Ottawa)
4100 Strandherd Drive, Suite 208
Ottawa, ON K2J 0V2

LMC (Calgary)
5940 Macleod Trail SW, Suite 102
Calgary, AB T2H 2G4

LMC Montreal (Ville St. Laurent)
6363 Transcanadienne, Suite 238
Ville Saint-Laurent, QC H4T 1Z9

LMC (Montreal Glen)
5325 Crowley Ave., Suite 301
Montréal, QC H4A 2C6

This consent form, a copy of which has been given to you, is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, you should feel free to ask. Please take the time to read this carefully and to understand any accompanying information.

INTRODUCTION

LMC Healthcare, in collaboration with Diabetes Canada and INTERVENT International, are involved in the Canadian Diabetes Prevention Program (the "CDPP"). The CDPP is a 12-month program that focuses on lifestyle and behaviour changes that works towards reducing your risk of developing type 2 diabetes. The CDPP is digitally based and each participant works individually with a health coach to reach their individual goals. In order to be eligible for the program, you either need to be diagnosed with prediabetes or are considered at high risk for diabetes from the CANRISK Questionnaire, or those age 45 or older with a BMI of 30 or greater.

We are asking you today to fill out the CANRISK Questionnaire to help determine your eligibility for this program. According to the Public Health Agency of Canada, CANRISK is a questionnaire that helps Canadians identify their risk of prediabetes or type 2 diabetes. Completing the questionnaire gives people an overall CANRISK score that predicts their risk of developing prediabetes or type 2 diabetes. The questionnaire is completed online via a web portal set-up especially for this purpose.

The questionnaire will ask you questions about yourself such as your age, gender, ethnicity, education level, weight, height, waist circumference, medical history and lifestyle. Your answers will be kept confidential. If your total score meets the inclusion criteria for the Program, you will then be provided further details on enrolling and continuing on with the Program.

BACKGROUND / RATIONALE:

According to Diabetes Canada ("DC"), in 2015, the estimated prevalence of prediabetes in Canada (>20 years of age) is 5.7 million people (22.1%). This rate is estimated to increase to 6.4 million people (23.2%) by 2025. Risk factors contributing to prediabetes and consequently Type 2 Diabetes include rising obesity rates, lack of physical activity, an aging population, and the cultural diversity of Canada .

There is convincing evidence that modifiable risk factors, such as diet and physical activity reduce the development of Type 2 Diabetes with the benefits extending beyond the active intervention stage. The underlying theory that supports this intervention relates to the imperative need to focus on weight loss and physical activity, with this population that is at risk of developing diabetes, due to its relationship with insulin resistance. DC outlines the importance of intensive and structured lifestyle modification to promote weight loss in order to reduce the progression of prediabetes to diabetes.

The following is applicable to those residing in all provinces except Alberta. Please see document applicable to Alberta below.

The proposed intervention would target participants who are identified as "at high risk" using the Canadian Diabetes Risk Assessment Questionnaire (CANRISK), or those age 45 or older with a BMI of 30 or greater, or those participants who have been diagnosed with prediabetes based on blood work.

PURPOSE/OBJECTIVE:
To reduce the risk of developing Type 2 Diabetes Mellitus by taking part in a 12-month lifestyle intervention program. A select group of participants, 452 participants, will have a follow up at 18 months to assess a post-study progression.

STUDY DESIGN:
Pre/post-single arm intervention study. This type of study is one in which there is a single arm, or one group measured before the intervention and again after the intervention. About 2,000 subjects will be enrolled in the Program.

About 1,500 subjects are expected to be in the program at this site.

The workshops will offer both complimentary education to assist with reinforcement of the educational material as well as support for the participants. The information in the webinars will be the same educational material that is found in the modules, but presented in a webinar format to reinforce learning.

All visits will take place via the INTERVENT Digital Platform, telephone/in-person. All data will be collected on the INTERVENT Digital Platform, including: baseline data (as stated above), two

STUDY PROCEDURES:
This agreement form is to obtain consent to use the CANRISK Questionnaire on the INTERVENT Digital Platform to compute:

1. Your CANRISK score
2. Determine your eligibility for the Canadian Diabetes Prevention Program
3. To use the information collected for research and statistical purposes

About 2,000 subjects will be enrolled in the Program.

At the beginning of the program, you will be asked to share information about yourself such as: medical history, social history, contact information, postal code, complete the comprehensive INTERVENT Health Assessment and fill out 6 other specific, subject-related questionnaires: 1) CANRISK Questionnaire 2) Knowledge Questionnaire, 3) 24 hour food recall, 4) Physical Activity Questionnaire and daily physical activity minutes, 5) Quality Of Life Questionnaire, & 6) Stages Of Change Questionnaire.

You will also be asked to have the following measurements done: your A1C (a blood test that provides an estimate of your blood sugar level over the past 3 months), fasting blood sugar, and cholesterol levels (a little less than 2 teaspoons of blood will be collected for these tests), weight, height, waist circumference, and blood pressure.

These measurements will be collected via one of two methods using a physical measurement protocol.

a. Performed by a health care professional during a home visit that you will schedule at your convenience.
b. Blood measures performed by a health care professional at a laboratory, and you will weigh and measure yourself using a scale and measuring tape. Your measures will be verified by providing a photograph of the scale and measuring tape result, or a live interaction over secure videoconferencing with study staff.

You will be given up to 6 weeks to complete the above information as well as answer a question about your commitment to the CDPP in order to continue on with the program.

All visits will take place via the INTERVENT Digital Platform, telephone/in-person. Before you use the INTERVENT Digital Platform and the content delivered from it, you will be required to review and accept INTERVENT's online participant services agreement and privacy policy. You will be acknowledging that INTERVENT-related data identifiable with you: a) will be kept in strict confidence (see below); b) will be used to deliver and support your participation in the CDPP; c) will be maintained in the United States and; d) that this CDPP is not medical care per se and supplements but does not replace your regular medical care. While the participant services agreement may include statements limiting your rights if you are harmed in this study, you do not release the investigator, sponsor, institution, or agents from responsibility for mistakes, and these statements, in Section 14 of INTERVENTS online participant services agreement, do not apply to the use of the INTERVENT Digital Platform in this research study. If you decide you do not want to agree, then you can decide not to participate in the study. In the event of any conflicts between various study-related documents, the provisions within this study consent govern your participation in the study.

Throughout the CDPP, you will be asked to complete the above questionnaires; fill out a Participant Satisfaction Survey at months 6 and 12; participate in a focus group or telephone Interview(s) to get your feedback on the program; and obtain repeat measurements (A1C, fasting blood sugar, cholesterol levels, weight, height, waist circumference, and blood pressure at 12 months. You may also be asked to repeat these measurements at 6 and 18 months to see short term and a longer term affect. At your coaching touch points, you will also be asked your weekly physical activity minutes as well as your weight and waist circumference.

STUDY DESIGN:
This type of study is one in which there is a single arm, or one group measured before the intervention and again after the intervention.

About 2,000 subjects will be enrolled in the Program. About 1,500 subjects are expected to be in the program at this site.

About the CDPP

The CDPP takes place over 12 months and includes both individual and group workshop education. Participants will have weekly telephonic sessions with a health coach for the first 3 months of the CDPP and monthly telephonic sessions with a health coach for the last 9 months of the program. If you would like to go to one of the LMC locations, an in-person session may be arranged.

The subjects and content of educational modules and topics are based on the course outline for the American led Center for Disease Control and Diabetes Prevention Program and are already created and widely used by INTERVENT. Founded in 1997, INTERVENT is a physician-led global health management company that is dedicated to optimizing the health of as many people as possible by offering affordable and cost-effective access to credible, evidence-based lifestyle management programs and chronic disease risk reduction services.

INTERVENT programs have been proven effective in numerous published studies, including randomized and independently-conducted clinical trials. More than two million individuals have participated in INTERVENT programs, including patients from over 120 medical centers in the United States and Canada as part of two recent multi-center clinical trials funded by the National Institutes of Health.

The CDPP is based on Canadian information and will be provided by health care professionals in Canada who are trained to deliver this Program using the INTERVENT educational topics and online application.

The CDPP is a personalized, lifestyle management program that empowers you to lead a healthier life and may reduce your risk for type 2 diabetes. Your personal health coach will guide and support you through the CDPP in a step-by-step manner. Together with your coach, you will set action goals, develop plans and actively engage in trying new healthy habits that are tailored to your needs, interests and personal circumstances. Between coaching sessions, you will be provided with online educational materials to complete and apply to your everyday life. Your health coach will help you be accountable for achieving the goals that are set. You will report your current weight, blood pressure and minutes of aerobic physical activity in the past week.

During the first three months of the program, you'll meet with your health coach weekly. During months four through 12, you'll have monthly coaching sessions. All coaching calls are via telephone appointments, unless you choose to have an in-person coaching session at one of

the LMC sites, which may be arranged if possible. You should keep all of your coaching appointments. During your first two sessions with your personal health coach, you will get to know each other, review the results of your baseline assessments and establish your personal wellness vision. These sessions are longer than other sessions and will require approximately 30 to 60 minutes. Other sessions will require 15 minutes.

The CDPP gives you access to the following:

- Twenty-two (22) private telephone (possible in-person) sessions with a personal health coach at times that are convenient for you
- Access to various health and wellness resources via the INTERVENT online platform:
  -Education modules covering healthy eating, physical activity, weight management, stress management and smoking cessation, if needed
  -Audio versions of the education modules
  -Personalized meal and exercise plans
  -Tools to track your eating, exercise and stress
  -Healthy recipes
  -Fun challenges and incentives, including drawings for prizes
- Monthly webinars on topics to support and expand upon what you learn in your coaching sessions

RISKS AND DISCOMFORTS:

By filling out this questionnaire, we will be able to determine if you are at risk for developing type 2 diabetes and eligible to participate in this study. If you are not eligible, there are alternatives available to you such as follow up with your family physician/health care provider(s).

If found eligible for the Program, before you enroll, we will more fully describe the Program to you and provide information about the Program's benefits, its potential risks and discomforts and the potential risks of not participating. By filling out the CANRISK questionnaire, you will help us to better understand people's risk of developing type 2 diabetes. We hope that what we learn from you can be used to help other people at risk for developing type 2 diabetes. You may be uncomfortable talking about some of the items on the questionnaire. There is also a possible risk of loss of confidentiality of your personal health information.

BENEFITS:

You may benefit as a result of your participation in completing this questionnaire. There is, however, no guarantee that you will benefit from your participation. Information learned from the study questionnaire may help other people in the future.

ALTERNATIVES TO PARTICIPATION:

Completing the questionnaire is for research purposes only. The only alternative is to not complete the questionnaire.

COSTS TO SUBJECTS:

There is no cost to you, your private medical insurance (if any), or the public health insurance plan, for your participation in this Program.

You will not receive any monetary compensation for completing the questionnaire.

COMPENSATION FOR INJURY:

In case of an injury or illness suffered by participating in this study, you will receive appropriate medical care from our Canadian healthcare system. The sponsor has no plans to cover the costs of any study-related injuries. By signing this document, you are not giving up your legal rights, nor releasing the study doctor or sponsors from their legal and professional obligations.

CONFIDENTIALITY:

All information disclosed or produced during the Program, including the CANRISK Questionnaire, will, at all times, be treated by the LMC and INTERVENT staff in a manner consistent with all applicable data privacy regulations and kept confidential, except where disclosure is required by law. The results of this research study may be presented at meetings or in publications but your identity will not be disclosed. As part of this research, the results of the questionnaire will be collected. The information collected will be kept confidential and only the Program staff will be able to review your records. A study doctor will review your blood measurements. In the event your lab values are elevated and require follow up by a doctor, a study doctor will contact you. Representatives of the research ethics review board – Advarra IRB (an independent ethics committee that reviewed the ethical aspects of this study to help protect the rights and welfare of study participants), may also have access to the information collected about you for this study, at the study site. While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the staff members to protect your privacy.

<u>Whom to Contact About this Study:</u>

During the study, if you have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00035919.

VOLUNTARY PARTICIPATION:

Your participation in filling out the CANRISK Questionnaire is completely voluntary. You have the right to withdraw from the Program at any time, without giving a reason, even if you have signed this consent form. If you do not take part or withdraw from the Program, you will not be penalized nor lose any benefits to which you are entitled. Your healthcare will not be affected.

Although you are not his/her patient, the study doctor may decide to withdraw you from the Program if your condition worsens, if you do not follow the doctor's instructions, if the study doctor feels it is in your best interests to be withdrawn, if the study sponsor discontinues the study, or for administrative reasons. You can be withdrawn without your consent, but the study doctor will tell you why.

SIGNATURE PAGE:

Confirmation of Electronic Agreement:

- I understand what I am being asked
- I understand that my agreement is voluntary and I may withdraw at any time without affecting my future care
- I understand that my participation is that of a participant filling out the CANRISK questionnaire and not of a patient receiving any medical care from the study doctor
- I understand that the information collected as part of the Program will be kept confidential, will be maintained in compliance with applicable laws and that my name will not be used on any future publications

The below is applicable to those residing in Alberta

CANRISK Questionnaire Informed Consent & Participant Agreement Form

Version 5.0 January 7, 2021

RESEARCH PROJECT AND TITLE: Prevention of Type 2 Diabetes using a Digital Wellness Coaching Intervention: The Canadian Diabetes Prevention Program

PROTOCOL NUMBER: Canadian Diabetes Prevention Program (CDPP)

PRIMARY INVESTIGATOR: Buki Ajala, MBBS, ScE Endo, FRCP (UK), FRCPC

SPONSOR: **LMC Health Care**

ADDRESS: **LMC Health Care (Calgary)**
3940 MacLeod Trail SW, Suite 102
Calgary, AB T2h 2G4

TELEPHONE: 403-288-3224

Study Support Representative:
Brad Lang, Project Manager
(416) 559-4665
Brad.Lang@LMC.ca

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To reduce the risk of developing Type 2 Diabetes Mellitus by taking part in a 12-month lifestyle intervention program. A select group of participants, 452 participants, will have a follow up at 18 months to assess a post-study progression.

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About 500 subjects are expected to be in the program at this site.

The workshops will offer both complimentary education to assist with reinforcement of the educational material as well as support for the participants. The information in the webinars will be the same educational material that is found in the modules, but presented in a webinar format to reinforce learning.

All visits will take place via the INTERVENT Digital Platform, telephone/in-person. All data will be collected on the INTERVENT Digital Platform, including: baseline data (as stated above), two Informed Consents, information about the participant (such as name, contact information, health card number, postal code), inclusion/exclusion criteria, all questionnaire data, and anthropometric data. The analysis will be within person comparison to assess change within the same person over the course of the study. There is no control group.

STUDY PROCEDURES:
This agreement form is to obtain consent to use the CANRISK Questionnaire on the INTERVENT Digital Platform to compute:

1. Your CANRISK score
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3. To use the information collected for research and statistical purposes

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Throughout the CDPP, you will be asked to complete the above questionnaires; fill out a Participant Satisfaction Survey at months 6 and 12; participate in a focus group or telephone Interview(s) to get your feedback on the program; and obtain repeat measurements (A1C, fasting blood sugar, cholesterol levels, weight, height, waist circumference, and blood pressure at 12 months. You may also be asked to repeat these measurements at 6 and 18 months to see short term and a longer term affect. At your coaching touch points, you will also be asked your weekly physical activity minutes as well as your weight and waist circumference.

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The CDPP is based on Canadian information and will be provided by health care professionals in Canada who are trained to deliver this Program using the INTERVENT educational topics and online application.

The CDPP is a personalized, lifestyle management program that empowers you to lead a healthier life and may reduce your risk for type 2 diabetes. Your personal health coach will guide and support you through the CDPP in a step-by-step manner. Together with your coach, you will set action goals, develop plans and actively engage in trying new healthy habits that are tailored to your needs, interests and personal circumstances. Between coaching sessions, you will be provided with online educational materials to complete and apply to your everyday life. Your health coach will help you be accountable for achieving the goals that are set. You will report your current weight, blood pressure and minutes of aerobic physical activity in the past week.

During the first three months of the program, you'll meet with your health coach weekly. During months four through 12, you'll have monthly coaching sessions. All coaching calls are via

telephone appointments, unless you choose to have an in-person coaching session at one of the LMC sites, which may be arranged if possible. You should keep all of your coaching appointments. During your first two sessions with your personal health coach, you will get to know each other, review the results of your baseline assessments and establish your personal wellness vision. These sessions are longer than other sessions and will require approximately 30 to 60 minutes. Other sessions will require 15 minutes.

The CDPP gives you access to the following:

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  - -Audio versions of the education modules
  - -Personalized meal and exercise plans
  - -Tools to track your eating, exercise and stress
  - -Healthy recipes
  - -Fun challenges and incentives, including drawings for prizes
- Monthly webinars on topics to support and expand upon what you learn in your coaching sessions

RISKS AND DISCOMFORTS:

By filling out this questionnaire, we will be able to determine if you are at risk for developing type 2 diabetes and eligible to participate in this study. If you are not eligible, there are alternatives available to you such as follow up with your family physician/health care provider(s).

If found eligible for the Program, before you enroll, we will more fully describe the Program to you and provide information about the Program's benefits, its potential risks and discomforts and the potential risks of not participating. By filling out the CANRISK questionnaire, you will help us to better understand people's risk of developing type 2 diabetes. We hope that what we learn from you can be used to help other people at risk for developing type 2 diabetes. You may be uncomfortable talking about some of the items on the questionnaire. There is also a possible risk of loss of confidentiality of your personal health information.

BENEFITS:

You may benefit as a result of your participation in completing this questionnaire. There is, however, no guarantee that you will benefit from your participation. Information learned from the study questionnaire may help other people in the future.

ALTERNATIVES TO PARTICIPATION:

Completing the questionnaire is for research purposes only. The only alternative is to not complete the questionnaire.

COSTS TO SUBJECTS:

There is no cost to you, your private medical insurance (if any), or the public health insurance plan, for your participation in this Program.

You will not receive any monetary compensation for completing the questionnaire.

COMPENSATION FOR INJURY:

In case of an injury or illness suffered by participating in this study, you will receive appropriate medical care from our Canadian healthcare system. The sponsor has no plans to cover the costs of any study-related injuries. By signing this document, you are not giving up your legal rights, nor releasing the study doctor or sponsors from their legal and professional obligations.

CONFIDENTIALITY:

All information disclosed or produced during the Program, including the CANRISK Questionnaire, will, at all times, be treated by the LMC and INTERVENT staff in a manner consistent with all applicable data privacy regulations and kept confidential, except where disclosure is required by law. The results of this research study may be presented at meetings or in publications but your identity will not be disclosed. As part of this research, the results of the questionnaire will be collected. The information collected will be kept confidential and only the Program staff will be able to review your records. A study doctor will review your blood measurements. In the event your lab values are elevated and require follow up by a doctor, a study doctor will contact you. Representatives of the research ethics review board – The Health Research Ethics Board of Alberta – Community Health Committee (HREBA-CHC) (an independent ethics committee that reviewed the ethical aspects of this study to help protect the rights and welfare of study participants), may also have access to the information collected about you for this study, at the study site. While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the staff members to protect your privacy.

Whom to Contact About this Study:

During the study, if you have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:** The Health Research

Ethics Board of Alberta – Community Health Committee at 780-423-5727 or toll-free at 1-877-423-5727. An REB is an independent committee established to protect the rights of research participants.

VOLUNTARY PARTICIPATION:

Your participation in filling out the CANRISK Questionnaire is completely voluntary. You have the right to withdraw from the Program at any time, without giving a reason, even if you have signed this consent form. If you do not take part or withdraw from the Program, you will not be penalized nor lose any benefits to which you are entitled. Your healthcare will not be affected.

Although you are not his/her patient, the study doctor may decide to withdraw you from the Program if your condition worsens, if you do not follow the doctor's instructions, if the study doctor feels it is in your best interests to be withdrawn, if the study sponsor discontinues the study, or for administrative reasons. You can be withdrawn without your consent, but the study doctor will tell you why.

SIGNATURE PAGE:

<u>Confirmation of Electronic Agreement:</u>

- I understand what I am being asked
- I understand that my agreement is voluntary and I may withdraw at any time without affecting my future care
- I understand that my participation is that of a participant filling out the CANRISK questionnaire and not of a patient receiving any medical care from the study doctor
- I understand that the information collected as part of the Program will be kept confidential, will be maintained in compliance with applicable laws and that my name will not be used on any future publications