CANADIAN HEART RESEARCH CENTRE

259 Yorkland Road, Suite 200
North York, Ontario, Canada M2J OB5

CONSENT TO PARTICIPATE IN A QUALITY ENHANCEMENT RESEARCH INITIATIVE

PROGRAM TITLE: ***CHOLESTABETES (CHOLESTerol lowering in type 2 diABETES) Quality Enhancement Research Initiative (QuERI)***

SPONSOR: Valeant Canada

CO-ORDINATING CENTRE & DATA MANAGEMENT: Canadian Heart Research Centre (CHRC)

PRINCIPAL INVESTIGATOR: Dr. Anatoly Langer

Before deciding whether or not to take part in this research program, it is important that you read the information in this consent form. It includes details you need to know in order to decide if you wish to take part. If you have any questions, ask the program doctor and/or research staff. You should not sign this form until you are sure you understand the information. All research is voluntary. You may also wish to discuss the program with a family member or close friend.

INTRODUCTION:

The CHOLESTABTEES QuERI is an observational quality enhancement initiative which provides guideline-based management strategies and feedback to physicians caring for patients with Type 2 Diabetes Mellitus (T2DM) who have not yet achieved guideline-recommended LDL-C (bad cholesterol) and A1C (average blood sugar level for the past two to three months) targets.

Approximately 75 primary care physicians across Canada will take part in this program and it is intended that approximately 375 patients with Type 2 Diabetes Mellitus whose LDL-C and A1C levels are above the guideline-recommended targets, will be enrolled.

PURPOSE:

The purpose of this program is to improve the management of patients with Type 2 Diabetes Mellitus and to help physicians gain more information about treatment options through a series of automated reminders which are aligned with the published Canadian recommendations for the management of patients with Type 2 Diabetes Mellitus. **THERE WILL BE NO INVESTIGATIONAL DRUGS USED.**

PROGRAM PROCEDURES:

Your participation is entirely voluntary. If you agree to participate in this program you will be asked to sign this consent form allowing access to your medical records through your primary care physician during the baseline (Visit 1) and during regularly scheduled follow-up visits. The follow-up visits will occur 14±6 weeks (Visit 2) and 24±6 weeks (Visit 3) after the baseline visit with your primary care physician. **THERE ARE NO ADDITIONAL PROCEDURES OR BLOOD DRAWS OF ANY KIND RELATED TO THIS PROGRAM.**

CANADIAN HEART RESEARCH CENTRE

259 Yorkland Road, Suite 200
North York, Ontario, Canada M2J OB5

RISKS/BENEFITS:

You will not undergo any extra tests or receive any extra treatments as a result of this program and all of the information will be obtained from your medical records.

You may not benefit directly from your participation. However, programs like this have been shown to improve patient management and outcomes.

CONFIDENTIALITY:

The program investigators and coordinators (hereby referred to as "program personnel"), the sponsoring company, **Valeant Canada** and **The Canadian Heart Research Centre** or designee(s) and Health Canada are committed to respecting your privacy. No other persons will have access to your personal health information or identifying information without your consent, unless required by law. Any medical records, documentation or information related to you will be coded using an ID number to ensure that persons outside of the program will not be able to identify you. In addition, electronic files will be stored on a secure network and will be password protected. The chance that this information will accidentally be given to someone else is small.

If the results of this program are reported in medical journals or at meetings, your name will not be identified. No information that discloses your identity will be published.

PARTICIPATION AND WITHDRAWAL:

You may decide not to take part in this program at any time, without any effect on your care. If you wish to withdraw your participation, you may contact your primary care physician directly and notify them of your decision. The quality of care you or your family receives at your primary care physician's office will not be affected in any way if you decide not to participate or if you withdraw from this program.

COMPENSATION:

You will not receive any payment for participating in this program. By signing this consent form, you do not waive any of your legal rights, nor release the study doctors, sponsors, or involved institutions from their legal and professional duties.

RESEARCH ETHICS BOARD CONTACT:

For information concerning your rights as a research participant, you should contact your family doctor, lawyer, or write to Optimum Ethics Review Board at 604 Taunton Rd. W., Oshawa, Ontario L1H 7K4 or by fax (905) 723-7590 or email: optimumerb@bellnet.ca.

CANADIAN HEART RESEARCH CENTRE

259 Yorkland Road, Suite 200
North York, Ontario, Canada M2J OB5

CONSENT TO PARTICIPATE:

Your signature on this consent form means that you have read this document and to the best of your knowledge and belief, you understand the information contained herein. You have been allowed to ask all of your questions and they have been answered to your satisfaction. If you have any further questions, you may call Dr. _____ at _____.

CANADIAN HEART RESEARCH CENTRE

259 Yorkland Road, Suite 200
North York, Ontario, Canada M2J OB5

INFORMED CONSENT FORM

PROGRAM TITLE:

CHOLESTABETES (CHOLESTerol lowering in type 2 diABETES) Quality Enhancement Research Initiative (QuERI)

I CONFIRM THAT I HAVE BEEN GIVEN SUFFICIENT TIME TO CONSIDER THE ABOVE INFORMATION AND TO SEEK ADVICE IF I CHOOSE TO DO SO. IN ADDITION, I CONFIRM THAT TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL TECHNICAL LANGUAGE USED BY THE RESEARCH TEAM MEMBERS HAS BEEN EXPLAINED AND THAT I RECEIVED SATISFACTORY ANSWERS TO ALL QUESTIONS WHICH I ASKED. I HAVE READ AND TO THE BEST OF MY KNOWLEDGE AND BELIEF, UNDERSTAND THIS CONSENT FORM AND I VOLUNTARILY AGREE TO PARTICIPATE IN THIS QUALITY ENHANCEMENT RESEARCH INITIATIVE (QuERI).
I HAVE RECEIVED A COPY OF THIS CONSENT FORM.

I _____ agree to participate in this QuERI program.
(please print your first and last name in block letters)

Signature of Participant: _____ Date: ____ (day) _____ (month), 20____ (year)

I certify that I have explained the purpose of this program to _____ (Participant's Name) and he (she) has signed the informed consent form in my presence.

_____
Printed Name & Position of Individual who conducted the Informed Consent Discussion

_____
Signature of Individual who conducted the Informed Consent Discussion

Date: ____ (day) _____ (month), 20____ (year)

Participant's Initials _____