



Patient Information and Informed Consent Form

INSERT STUDY TITLE HERE

Investigator: INSERT INFORMATION HERE

Co-investigator(s): INSERT INFORMATION HERE

Sponsor: INSERT INFORMATION HERE

This consent form may contain words that you do not understand. Please ask the study investigator(s) or the study coordinator(s) to explain any words or information that you do not clearly understand.

Introduction

You are being asked to take part in a research study sponsored by INSERT INFORMATION HERE (the ‘sponsor’). Before you decide whether or not to take part in the study you should read this information. It is very important that you read and understand the following patient information sheet. This form explains the study, including the risks and benefits of taking part in the study. You will be given this information sheet to keep. Please feel free to ask the study investigator(s) or research staff any questions that will help you understand the study and what you are expected to do. Before you agree to take part in this study, you may take this information home and discuss it with a family member or your family doctor. If you are a First Nations person, or an indigenous person who has contact with spiritual “elders” you may want to talk with them before you proceed with being part of this study. Please ask if there is anything that is not clear to you or if you would like more information before deciding whether or not to take part in the study.

Up to INSERT SUBJECT NUMBER HERE subjects with INSERT MEDICAL CONDITION (if applicable) HERE will be included in the study at this site, which will take place in Kingston, Ontario. The study has been reviewed for ethical compliance by the Queen’s University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board. This group is responsible for safeguarding the safety, rights and well-being of human subjects participating in clinical trials. The trial will be conducted in keeping with international quality standards which have been adopted by Health Canada.



Purpose of the Study

You are being asked to participate in this research study because you have been diagnosed with **INSERT MEDICAL CONDITION HERE**. In this section:

- Explain what the study drug being used in the study is and how it could improve the condition of the patient participating in the research study;
- Explain how many subjects at this site and elsewhere will be participating;
- Usually include a statement for investigational drugs that states *“The medication being tested in this study is currently not “on the market” (available for you to buy) in any country and therefore, will not be available to you after the study ends”*;
- Explain what the purpose/aims of the study are;
- Briefly explain the drug dosage (How much? How often? Route of administration?).

Voluntary Participation and Withdrawal

Your participation in this study is voluntary and you will be given adequate time to decide whether you wish to participate in this study. You may decline to participate or are free to withdraw from the trial at any time without reason, without penalty or loss of benefits to which you are otherwise entitled. Your decision to decline to participate or withdraw will not affect the standard of care you receive or your relationship with your investigator(s). If you do not wish to participate or if you withdraw from the trial, neither your current nor future medical care will be adversely affected. If you do decide to leave the study however, we would like you to attend one final visit to assess most of the procedures that were planned for the final visit. This is important for your safety and well-being. In addition, all unused study medication must be returned at this time.

If you agree to participate in the trial, the investigator(s)/study coordinator(s) will ensure, with your agreement, that your family doctor is informed about your participation. The investigator(s) may also remove you from the study at any time without your consent for reasons that include: your failure to follow study requirements; the occurrence of unusual or serious side effects; anytime the investigator(s) thinks it is in your best interest; the study has ended; and/or at the request of the study sponsor. If this were to happen, you would be informed of the reason(s). You will be informed promptly of any important findings that develop with **INSERT STUDY DRUG NAME HERE** during the course of the study, which might change your decision to continue in the study.



Benefit from Participating in this Study

All tests, examinations, and medical care required as part of this study will be provided at no cost. Moreover, other patients with **INSERT MEDICAL CONDITION HERE** may benefit from the overall conclusion to be drawn from the results of this study. There is no guarantee that you will receive any medical benefit from participating in this study.

Alternative Treatments

You do not need to participate in this study to receive treatment for your **INSERT MEDICAL CONDITION HERE**. Your investigator(s) will discuss these alternatives with you.

Study Procedures

During the study you will be asked to participate for up to **INSERT TIME FRAME**. The study comprises of **INSERT NUMBER OF CLINIC VISITS** to the laboratory that occur at designated time intervals. Each clinic visit will last from **INSERT TIME FRAME** in duration (see Appendix 1 for sample chart to include in the Information and Consent Form).

All procedures will be carefully explained by the investigator(s)/study coordinator(s) and you should ask whenever you need more information. You must provide consent to participate in this study before you can perform any study-related procedures. **INSERT ALL TYPES OF TESTS AS WELL AS HOW THE TESTS ARE PERFORMED HERE.**

INSERT ALL SPECIAL INSTRUCTIONS (especially withholding of certain medications) FOR VISITS HERE. Include a statement (if applicable) indicating to subjects that if they forgot to withhold certain medications on the day of their clinic visit that they must contact the investigator(s)/study coordinator(s) as your visit may need to be rescheduled and that it is important that subjects notify the investigator(s)/study coordinator(s) of any changes in your medications during the study, as this information will be noted in your medical record and may affect further participation in the study.

Clinic Visits

Insert here a detailed account of what will happen at each study visit (i.e. step by step breakdown of visit) during the screening, treatment, and follow-up period. An example includes the following:

Screening Period (Visits 1-3)



The *Screening Period* will last from 2-3 weeks depending on whether or not you have previously used certain medications prior to entry into the study. During this time the study staff will evaluate whether you are eligible to participate in the study and collect baseline medical information. You may be asked to stop taking certain medications throughout the study after Visit 1. You will not take any study medication during this period. These visits will last about 1 hour to 3 hours. The following procedures and activities will be performed to determine if you qualify:

Screening Visit 1

During the first screening visit, study personnel will complete the following procedures:

- Explain to you the purpose of this research study in detail. If you are willing to participate in the study you will be asked to sign and date the informed consent form;
- Review a specific set of criteria to determine if you are eligible to participate in the study;
- Record your demographic information and medical history;
- Perform a physical examination including heart rate, blood pressure, weight and height to make sure that you do not have any physical or medical problems that would prevent you from safely participating in the study;
- Perform an electrocardiogram (ECG), a simple test that records information about the electrical activity of your heart;
- Ask you questions about your smoking habits;
- Withdrawn some blood to detect what might prevent you from safely participating in the study;
- For women of childbearing age, a urine sample will be collected to make sure you are not pregnant;
- Perform a breathing test, exercise test, and body composition test;
- Record any adverse events that occurred in the previous week(s);
- Record any medication that you took in the previous week(s);



- Administer questionnaires;
- Instruct you on the completion of a subject diary/report card;
- Instruct you on what will occur at your next clinic visit and assign an appointment (date/time).

Potential Risk and Discomforts

Your progress in the study will be carefully monitored to ensure your safety and well-being. The investigator(s) will be available to respond to you if you feel worse. It is possible that you may experience side effects from the study medication. Or, the medication may have no beneficial effect and as a result you may feel that your condition is not improving or may be worsening. Inform your investigator(s)/study coordinator(s) immediately if this occurs, and he/she will assess your condition and make changes to your treatment if it is required. If necessary, you will be withdrawn from the study.

It is very important that you take your study medication in the manner that your investigator(s)/study coordinator(s) has described. If you miss any dose(s) you must tell the investigator(s)/study coordinator(s) at your next visit to the clinic. Please remember to return your partially used or empty medication to the investigator(s)/study coordinator(s) at each visit. Before taking any new prescription or non-prescription medication while on study, please consult your investigator(s)/study coordinator(s).

A. INSERT NAME OF STUDY DRUG:

Explain all possible side effects and risks associated with the study drug. This information is usually provided by the industry sponsor and can be inserted here.

B. INSERT NAME(S) OF ALL OTHER ITEMS ADMINISTERED TO SUBJECTS:

Explain all possible side effects and risks associated with other drugs, devices, vitamins, minerals and supplements given to the subjects while participating in the study. This information is usually provided by the industry sponsor and can be inserted here.



C. Other Medicines:

Explain all possible side effects and risks associated with withholding of certain medications while participating in study.

D. Pregnancy:

Explain all possible side effects and risks associated with becoming pregnant or fathering a child while participating in the study.

E. Tests/Procedures:

Explain all possible side effects and risks associated with all tests and procedures utilized in the study (i.e. laboratory tests, diagnostic tests). Be sure to include any devices given out to subjects to utilize at home for subject diaries (i.e. activity monitors, blood pressure monitors).

Trial-Related Injury

If you become ill or injured as a direct result of participating in this study, necessary medical treatment will be available at no additional cost to you. Your signature on this form only indicates that you have understood to your satisfaction the information regarding your participation in the study and agree to participate as a subject. In no way does this waive your legal rights nor release the investigator, the study sponsor or involved institutions from their legal and professional responsibilities.

Compensation

You will receive up to **INSERT AMOUNT HERE** for the completed study to compensate for travel, food and other reasonable out of pocket expenses that are directly related to your participation in the study. There will be no cost to you, to any private medical insurance, or to the public health insurance plan for study procedures for your participation in the study. There will be no charge to you for the study medication or any other tests done as part of the study.

The investigator is being compensated by the sponsor for his participation in the trial for direct costs associated with the study (i.e. salaries of the research associate(s) and principal investigator/sub-investigator for carrying out all study-related procedures, cost of performing procedures (i.e. laboratory services, breathing tests, exercise tests), equipment and supplies costs, travel and publication costs, and any other unforeseen costs that may arise within the



study). The institutions to which the study is being conducted, Queen’s University and Kingston General Hospital, is being compensated by the sponsor for its participation in the trial for indirect costs associated with the study (i.e. occupancy cost, building use, central administration, library cost, central computing services costs and any other unforeseen costs that may arise within the study).

Confidentiality

All medical records and research materials in which you are identified will be kept confidential and will not be made publicly available, unless required by applicable laws and/or regulations and will only be used for the purpose of the research study as stated in the study objectives above. For this study, the investigator(s)/study coordinator(s) will need to access your personal health records for health information such as past medical history and test results. If you agree, the investigator(s)/study coordinator(s) may also contact your family physician and your other health care providers to obtain additional medical information.

To make sure that the health information collected in this study is accurate, it will need to be checked from time to time against your medical records. A limited number of representatives from the study sponsoring drug company, **INSERT SPONSOR’S NAME HERE**, the research ethics review board, government regulatory authorities including Health Canada, the US Food and Drug Administration (FDA) and other foreign regulatory agencies may need to see these records in order to monitor the research and verify the accuracy of the study data. Your medical records may be examined in connection with this study or further analyses related to it. The results of the study may be published in a professional journal or presented at scientific meetings or to government regulatory authorities; however, your identity will NOT be disclosed in those presentations. If you decide to withdraw from this study, your medical records will be made available as described above.

By signing this consent form, you are authorizing the collection, use and disclosure of information, reporting, and transfer of data collected from this study, including personal data such as your date of birth, to **INSERT SPONSOR’S NAME HERE** and regulatory authorities within and outside Canada for the purposes of this study and further analyses related to it. On documents, your date of birth and assigned study number will only identify you. Your name will not be disclosed outside the research clinic. You have the right to look at your medical records and correct any errors about yourself by contacting the principal investigator, unless this is not allowed by applicable laws.

Subject’s Responsibilities

List all responsibilities of the subject for participating in this study. Examples include, but not limited to:



- If you are treated by another doctor (for example, in an emergency) you should inform them of your involvement in this study.
- You will not be allowed to participate in any other investigational drug studies while you are involved in this study.
- You must follow the instructions provided by the investigator(s)/study coordinator(s) and come to all scheduled study visits and be reasonably available for contact by phone if needed.
- You must bring your unused study medication, all empty containers, and completed study diaries to each of your study visits as well as an explanation for any lost or missing study medication.
- If you decide to drop out or are withdrawn from this study you will be asked to come in as soon as possible after taking your last dose of study medication and have a final physical examination. The doctor will ask about any medications you are taking and how you are feeling.
- You may be asked not to take some of your usual medications for certain periods of the study. If you are not able to go without your medication(s) before your appointment, you should resume or continue taking the medications and reschedule your testing day appointment.
- If during the study a change in your usual medications is necessary; you are asked to inform the study doctor in advance. The interaction with certain medications and the study drug is unknown and certain medications are not allowed in this study.
- You must tell the investigator(s)/study coordinator(s) about any changes in your health or problems that you are having.
- You must tell the investigator(s)/study coordinator(s) about any medications or remedies, including natural or herbal products, which you are taking even if they are obtained without a prescription.

Further Information

You have the right at any time to request information from the investigator(s) about your condition. You may also request that any other person, including your personal doctor, be given this information and a copy of this form.



During the course of any research project, new information may become available. If this happens, your investigator(s)/study coordinator(s) will tell you about it, and discuss with you whether you want to continue taking part in the study. If you decide to withdraw, your investigator(s)/study coordinator(s) will arrange for your continued care. If you decide to continue taking part you will be asked to sign a new consent form that the local research ethics board committee has approved.

Under certain circumstances your investigator(s) or the sponsor may decide to take you out of the study. Circumstances when this may occur include:

- a) You do not follow the directions of the investigator(s)/study coordinator(s) fully;
- b) You develop a serious illness that is not related to the study;
- c) Your investigator(s) decides that the study is not in your best interests;
- d) The sponsor, the regulatory agency or ethics committee decides to stop the study;
- e) You become pregnant, intend to become pregnant, are nursing a child during this study or intend to father a child.

If you do finish the study early for any of the above reasons you will be asked to attend a final visit to ensure your safety and complete the collection of study data.

**PLEASE TAKE A COPY OF THIS INFORMATION
AND CONSENT FORM HOME WITH YOU**

If you have any questions about your rights as a research subject, please contact Dr. Albert Clark (Chair of the Research Ethic Committee) at the Office of Research Services at Queen's University, Kingston at (613) 533-6081.

If you have any questions during the study, or if you experience any side effects, please contact:

INSERT PRINCIPAL INVESTIGATOR'S NAME and TELEPHONE HERE
INSERT CO-INVESTIGATOR(S) NAME and TELEPHONE HERE
INSERT STUDY COORINATOR'S NAME and TELEPHONE HERE
INSERT BACK-UP STUDY COORINATOR'S NAME and TELEPHONE HERE
INSERT DEPARTMENT HEAD'S NAME and TELEPHONE HERE
Dr. Albert Clark (Chair of the Research Ethic Committee): (613) 533-6081



APPENDIX 1: SCHEDULE OF ACTIVITIES

VISITS	Visit Number							
	Screening Period			Treatment 1 Period		Washout	Treatment 2 Period	
	1	2	3	4	5	6	7	8
Study Days	-21 to-15	-14	-9 to -4	0	21	36 to 39	42	63
Informed consent signed.*	X							
Review of current medications used.	X							
Review inclusion/exclusion criteria with subject.	X	X	X	X				
Medical history.	X							
Demographics (race, date of birth, gender) recorded.	X							
Smoking history and current smoking status recorded.	X							
Complete physical examination that includes blood pressure, oxygen levels, heart rate (pulse) check, weight, height.	X							X
Brief examination that includes blood pressure, oxygen levels, heart rate (pulse) check, weight.		X	X	X	X	X	X	
Review of any side effects or changes in medical condition (i.e. adverse events) or changes in medications since last visit.		X	X	X	X	X	X	X
12-lead electrocardiogram (an ECG to look at the subject's heart's activity).	X**	X**	X**	X	X	X	X	X
Blood and urine analysis.	X			X	X		X	X
Pregnancy test (women only). ***	X							X
Questionnaires completed.	X			X	X		X	X
Diary Training.	X							
Return and review of Diary.		X	X	X	X	X	X	X
Study drug provided.				X			X	
Return of study drug.					X			X

* The informed consent will be signed prior to any study procedure performed. ** Assessments conducted to familiarize subjects to study test procedures.
 *** The pregnancy test will be performed on all women of child-bearing potential unless a subject is >60 years old or >1 year post-menopausal or had a total or partial hysterectomy or tubal ligation.



PATIENT INFORMED CONSENT FORM

- I have read and I understand the information in this form that describes the purpose and nature of this study.
- The investigator or his delegate has discussed this study with me. I have been given ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the trial. I have received answers that fully satisfy all my questions.
- I understand that if I do not participate or if I discontinue my participation, I will not lose any benefits nor will I lose any legal rights if I decide to discontinue.
- I understand that my participation in this study is completely voluntary and that I am free to withdraw from this study at any time without having to give a reason for withdrawing.
- I realize that it is my responsibility to report to the investigator(s)/study coordinator(s) all changes in my physical or mental condition during the study.
- Having read, initialed, and dated all 12 pages of this patient information and consent form and understanding the requirements of the study; my signature below indicates that I voluntarily consent to participate in this study and allow access to my personal medical records, provided that confidentiality is maintained.
- I understand that I will receive a copy of this patient information and consent form.

Notification to Your Physician

Please indicate below whether you want us to notify your primary care physician or your specialist of your participation in this study.

- Yes, I want my primary care physician/specialist informed of my participation.
- No, I do not want my primary care physician/specialist informed of my participation.
- I do not have a primary care physician/specialist.
- The investigator(s) is my primary care physician/specialist.

Subject Name (Please print)	Subject Signature	Date (DD/MMM/YY)
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Name of Person Conducting Consent Process (Please print)	Signature of Person Conducting Consent Process	Date (DD/MMM/YY)
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Name of Principal Investigator (Please print)	Signature of Principal Investigator	Date (DD/MMM/YY)
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Insert Research Site Contact Information (Address, Telephone, Email)



*** PLEASE PERSONALLY DATE YOUR SIGNATURE**



Statement of the Investigator

The above-mentioned subject has been explained the nature of this study, the known risks and possible benefits involved in participating in this study, the alternative treatments, that he/she has the option to participate in this study and may withdraw at any time without affecting their usual medical care.

I, or one of my medical colleagues, will be available at any time for emergency purposes.

Name of Principal Investigator
(Please print)

Signature of Principal Investigator

Date (DD/MMM/YY)

*** PLEASE PERSONALLY DATE YOUR SIGNATURE**