Centre de recherche
Hôpital Charles LeMoyne
Centre affilié universitaire
et régional de la Montérégie
UNIVERSITÉ DE SHERBROOKE

# INFORMED CONSENT FORM

**PROJECT NO:** **-HCLM-09-***

**PROJECT TITLE OF THE STUDY:**

**PROTOCOL:**

**SPONSOR:**

**PRINCIPAL INVESTIGATOR:**

**PRINCIPAL INVESTIGATOR'S DEPARTMENT:**

**ADDRESS:** Hôpital Charles LeMoyne
3120, boul. Taschereau
Greenfield Park (Québec) J4V 2H1

**TELEPHONE:** (450) 466-5000, extension XXXX
(514) 406-XXXX pager

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***OBLIGATORY text for inapt subjects:***
(Note: This form is addressing the patient. However, it is possible in case of sudden incapability to give consent that the form be given to his/her representative through whom this form will be addressing the patient, even if he is unconscious or unable to communicate.)

## INTRODUCTION

*Suggested text:*
You are being asked to take part in a research study. Before you decide it is important for you to understand why the research is being done, how your information will be used, what the study will involve and the possible benefits, risks and discomforts. Please take time to read the following information carefully and once you have been fully informed about the study and had any questions answered, you will be asked to sign this form if you wish to participate.

## PURPOSE OF THE STUDY

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3120, boul. Taschereau, Greenfield Park (Québec) J4V 2H1
Téléphone (450) 466-5024 Télécopieur (450) 466-5025
Site Internet : www.santemonteregie.qc.ca/hclm

## PROCEDURES

*

## RISKS, SIDE EFFECTS AND DISADVANTAGES

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## WOMAN IN AGE TO PROCREATE (← use this title if study applies only to women) OR PERSON IN AGE TO PROCREATE (← use this title if study applies to both men and women)

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## BENEFITS AND ADVANTAGES

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## OTHER POSSIBLE TREATMENTS

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## COSTS/REIMBURSEMENT

***Suggested text:***
You will not receive any payment for your participation in this study. There will be no costs to you for participating in this study. The drugs will be provided to you free of charge as long as you will receive treatment within the framework of this study. We will refund you reasonable expenses caused by the follow-up visits for this study (parking, travel expenses, meals).

## COMPENSATION IN THE EVENT OF DAMAGE

***OBLIGATORY text:***
If you suffer any prejudice as a result of administering a drug or other procedures related to the study, you will receive all the care and services required by your state of health, without cost to you. By agreeing to participate in this study, you will not waive any of your rights nor release the researchers (if any: organizations, businesses) or institutions of their legal and professional responsibilities.

## CONFIDENTIALITY

***Suggested text:***
You also allow us to collect, gather and transmit - to... (name of company and its affiliated) like to the organizations of regulation of Canada and other countries - data collected within the framework of this study, including personal information: date of birth, sex and initial, for purposes of the study and the analyses which are associated with it.

***OBLIGATORY text:***
By signing this consent form you authorize the investigator to provide your coordinates to the Medical Record's department of Charles LeMoyne Hospital for the purpose of maintaining an institutional register to identify all subjects of the hospital that participated in a research study.

This register is among some of the measures established, by the Ministry of Health and Social Services, for your protection. This will allow the hospital, should the need be, to contact you. None of the information collected from this register will serve research and all information will be destroyed at the latest 12 months following the end of this research study.

## VOLUNTARY PARTICIPATION/WITHDRAWAL

***Suggested text:***
Your participation in this study is voluntary. You may thus refuse to participate. You may also withdraw from the study at any time, without giving a reason, simply by notifying the investigators or a member of the study team. All new knowledge acquired during the course of the study, which could affect your decision to continue to take part in it, will be communicated to you without delay.

Your decision not to participate or your withdrawal from the study will have no consequences on your future medical care or to your relationship with your doctor or other professionals.

Your doctor or investigator may withdraw you from the study at any time if he or she feels it is in your best interest, without first obtaining your consent.

Should you decide to withdraw from the study at any time, information collected on you up until that point will still be provided to _____.

## CONTACT NAME

***OBLIGATORY text:***
Should you have any questions concerning the study, you may contact Dr _____, Principal Investigator, or Study Coordinator at (450) 466-5000, extension XXXX or pager no (514) 406-XXXX. In case of an emergency, you can reach the _____ on duty, 24 hours a day by calling (450) 466-5000 extension 0. The receptionist of the hospital will transfer your call to the _____ on duty.

If you wish to obtain additional information regarding your rights as participant in a research project or regarding any damage attributable to the research, harmful side effects to your health, you may contact the secretary of the *comité d'éthique de la recherche de l'Hôpital Charles LeMoyne* by calling (450) 466-5000 extension 2564.

In addition, if you have any complaints as a research participant and wish to communicate with a third impartial party, you may call the Service Quality and Complaints Commissioner of Charles LeMoyne Hospital at (450) 466-5434.

# STUDY FLOW CHART

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## ADDITIONAL AUTHORIZATIONS

***Specific authorization or refusal examples :***

TAPED INTERVIEW

☐ **Yes, I accept** that the individual or family interview be taped for this study.

| Subject's signature | Name (Print) | Date |
|---|---|---|

☐ **No**, **I do not accept** that the individual or family interview be taped for this study.

| Subject's signature | Name (Print) | Date |
|---|---|---|

AUTHORIZATION TO INFORM MY FAMILY DOCTOR OF MY PARTICIPATION IN THIS STUDY

☐ **Yes, I want** the study doctor to inform my family doctor/specialist of my participation.

| Subject's signature | Name (Print) | Date |
|---|---|---|

☐ **No, I do not want** the study doctor to inform my family doctor/specialist of my participation in this study.

| Subject's signature | Name (Print) | Date |
|---|---|---|

☐ **I do not have** a family doctor/specialist.

| Subject's signature | Name (Print) | Date |
|---|---|---|

☐ **The study doctor** is my family doctor/specialist.

| Subject's signature | Name (Print) | Date |
|---|---|---|

**BLOOD SAMPLE**

☐ **I agree** to give a sample of my blood to the associated laboratories (name of pharmaceutical company) for this study.

| Subject's signature | Name (Print) | Date |
|---|---|---|

☐ **I do not agree** to give a sample of my blood to the associated laboratories (name of pharmaceutical company) for this study.

| Subject's signature | Name (Print) | Date |
|---|---|---|

## CONSENT STATEMENT

***Suggested text:***

The nature, the procedures, the risks and the benefits associated with my participation in this research study, as well as the confidential aspects of the information collected during the study, has been explained to me by a member of the study team.

I have had the opportunity to ask all my questions concerning the different aspects of the study, and I have received satisfactory answers.

I acknowledge that I had ample time to make my decision.

I voluntarily agree to participate in this study. I am free to withdraw at any time, without in any way affecting my relationship with my doctor or other professionals, and without prejudice of any kind.

I will be given a signed and dated copy of this informed consent form and the original will be placed in my medical chart.

| | | |
|---|---|---|
| Subject's signature | Name (Print) | Date / Time (if needed) |
| Witness' signature | Name (Print) | Date/ Time (if needed) |
| Signature of person who administered informed consent | Name (Print) | Date/ Time (if needed) |

***OBLIGATORY page for inapt subjects:***

**CONSENT FORM FOR THE PERSON REPRESENTING THE PATIENT WHO HAS A SUDDEN INCAPABILITY TO GIVE CONSENT**

Since Mr./Mrs. _____ has been rendered suddenly incapable of giving his/her consent for reasons mentioned below, Quebec's Civil Rights Code ( articles 15 and 21 ) authorizes you, as his/her _____ ( your relation to the patient ), to consent on his / her behalf to participate in this study. Your decision should be based on what you think the patient would have decided, had he made the decision for him / herself, or still, what you think is in this patient's best interest.

As soon as Mr./Mrs. _____'s condition will have sufficiently improved, we will ask him/her to sign the patient's consent form so he/she can signify his/her will to continue his/her participation to the study.

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**REASON (S) FOR THE PATIENT'S SUDDEN INCAPABILITY TO GIVE CONSENT:** _____

_____

_____
Name of representative and relationship (Print)

_____ _____ _____
Signature of representative Date Time

_____
Name of witness (Print)

_____ _____ _____
Signature of witness Date Time

_____
Name of person who administered informed consent (Print)

_____ _____ _____
Signature of person who administered informed consent Date Time