# *[Institutional Logo(s)]*

# PARTICIPANT INFORMATION AND CONSENT FORM

**STUDY TITLE**

**PRINCIPAL INVESTIGATOR**

**SUB-INVESTIGATORS and/or STUDENT RESEARCHERS**

**SPONSOR [or Funding Agency]**

**Contact Phone Number**

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**INTRODUCTION**

You are invited to take part in this research study because you ……

Your participation is voluntary. It is up to you to decide whether or not you wish to take part. If you wish to participate, you will be asked to sign this form. If you do decide to take part in this study, you are still free to withdraw at any time and without giving any reasons for your decision.

If you do not wish to participate, you will not lose the benefit of *{any medical care, employment, or academic standing, as applicable}* to which you are entitled or are presently receiving. It will not affect your relationship with *{PI}.*

Please take time to read the following information carefully. You can ask the researcher to explain any words or information that you do not clearly understand. You may ask as many questions as you need. Please feel free to discuss this with your family, friends or family physician before you decide.

**WHO IS CONDUCTING THE STUDY?**

Scenario #1 wording:

The study is being conducted/sponsored by the [*name of research group, e.g., Industry sponsor/Granting agency].*The [*researchers, and institutions, as applicable*] are being paid to conduct this research study.

Scenario #2 wording:

The sponsor of this study [*name*] will reimburse [*study doctor and the institution*] for the costs of undertaking this study. However, neither the institution nor any of the investigators or staff will receive any direct financial benefit from conducting this study.

Note: If your study is unfunded, this section can be left out.

**WHY IS THIS STUDY BEING DONE?**

This study is being done because … *{add brief explanation of the research problem}*

**WHO CAN PARTICIPATE IN THE STUDY? (if applicable)**

You are eligible to participate in this study if … *{add a brief description of the exclusion and inclusion criteria}*

**WHAT DOES THE STUDY INVOLVE?**

*Describe in lay language the overall design of the study. Then, describe in details ALL of the research-related procedures. Potential research participants should be clearly informed of the extent of their involvement at each step of their participation. They should also be told the expected time commitment for each step of the project in which they will be involved.*

**WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?**

If you choose to participate in this study, there *… {may or may not be direct benefits* *to you}*. It is hoped the information gained from this study can be used in the future to benefit other people with a similar condition. *{add a list of any potential benefits that participants may receive because of their participation}*

**ARE THERE POSSIBLE RISKS AND DISCOMFORTS?**

If you choose to participate in this study, the following are possible … *{add a list of any potential risks or discomforts that participants may face due to their participation}*

**WHAT IF NEW INFORMATION BECOMES AVAILABLE THAT MAY AFFECT MY DECISION TO PARTICIPATE?** *{if applicable}*

During the course of this study, new information that may affect your willingness to continue to participate will be provided to you by the researcher.

**WHAT HAPPENS IF I DECIDE TO WITHDRAW?**

Your participation in this research is voluntary. You may withdraw from this study at any time. You do not have to provide a reason. There will be no penalty or loss of benefits if you choose to withdraw. Your future medical care *{or employment or academic status, as applicable}* will not be affected.

If you choose to enter the study and then decide to withdraw later, all data collected about you during your enrolment will be retained for analysis.

**WILL I BE INFORMED OF THE RESULTS OF THE STUDY?**

The results of the study will be available *{time}* from *{Principal Investigator or web site, etc}*

*Also, provide information on how results will be disseminated (i.e. thesis, articles, reports, etc.*

**WHAT WILL THE STUDY COST ME?**

Scenario #1: No Honorarium not provided

You will not be charged for any research-related procedures. You will not be paid for participating in this study. You will not receive any compensation, or financial benefits for being in this study, or as a result of data obtained from research conducted under this study.

Scenario #2: Expense Honorarium Provided

You will not be charged for any research-related procedures. You will not be paid for participating in this study. An honorarium of *{$xxx}* will be provided to cover your time and out-of-pocket expenses such as travel, parking or meals. If you decide to withdraw early from this study, your compensation will be proportional to your time in the study. You will not receive any compensation, or financial benefits, for being in this study, or as a result of data obtained from research conducted under this study*.*

**WHAT HAPPENS IF SOMETHING GOES WRONG?** *{if applicable}*

By signing this document, you do not waive any of your legal rights.

**WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?**

In Saskatchewan, the *Health Information Protection Act (HIPA)* defines how the privacy of your personal health information must be maintained so that your privacy will be respected. *{if applicable}*

Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent to the disclosure. However, research records and medical records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of (Insert here, if relevant to study**,** the name of the sponsoring company), Health Canada, (Insert here, if relevant to study**,** the U.S. Food and Drug Administration), and the {institutional} Research Ethics Board for the purpose of monitoring the research. However, no records, which identify you by name or initials, will be allowed to leave the Investigators' offices. The results of this study may be presented in a scientific meeting or published, but your identity will not be disclosed.

**WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?**

If you have any questions or desire further information about this study before or during participation, you can contact *{Principal Investigator or his/her representative}* at *{telephone number}*.

If you have any concerns about your rights as a research participant and/or your experiences while participating in this study, contact the Chair of the University of Regina Research Ethics Board, at 306-585-4775(out of town callers may call collect). The Research Ethics Board is a group of individuals (scientists, ethicists, and members of the community) that provide an independent review of human research studies. This study has been reviewed and approved on ethical grounds by the University of Regina Research Ethics Board.

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**CONSENT TO PARTICIPATE**

**Study Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

* I have read (or someone has read to me) the information in this consent form.
* I understand the purpose and procedures and the possible risks and benefits of the study.
* I was given sufficient time to think about it.
* I had the opportunity to ask questions and have received satisfactory answers.
* I understand that I am free to withdraw from this study at any time for any reason and the decision to stop taking part will not affect my future relationships.
* I give permission to the use and disclosure of my de-identified information collected for the research purposes described in this form.
* I understand that by signing this document I do not waive any of my legal rights.
* I will be given a signed copy of this consent form.

I agree to participate in this study:

Printed name of participant: Signature Date

Printed name of person obtaining consent: Signature Date