

Preparing a Consent Form

The consent form is one aspect of a process to inform a potential research participant so that he/she can make a decision about participation in a study. Consent begins when a potential participant is first informed of the existence of a study and ends some time after its conclusion. The consent form is an important part of this process.

The consent form has the following objectives:

1. It is an **information tool**. In theory, it is read carefully by a potential research participant before agreeing to participate. It is not a substitute for good communication between the researcher and a potential participant.
2. It is a **reference document** that allows a research participant to follow the progress of a study step by step. As such, the consent form promotes adherence and retention in that a research participant does not have to remember everything and is less likely to get confused.
3. It reminds the research participant of relevant **legal rights**.
4. It is a **source of information for the researchers** in outlining all of the information that must be communicated to a potential research participant and how to communicate that information.

There are four essential elements in a consent form:

1. The voluntary nature of participation and the right to withdraw from a study at any time are the cornerstones of the consent process and must be stated unequivocally.
2. There must be a clear and understandable description of the purpose of the study and of all the procedures so that a potential research participant is informed of the extent of his/her involvement at each step of the study.
3. There must be a comprehensive description of the benefits and risks associated with the study.
4. There must be an indication of how the researcher intends to safeguard the anonymity of the participant and the confidentiality of the information collected.

The following document provides a step by step description of each element of a consent form and why it is required in some studies. **It is intended as a guide only. Not all elements are necessary or required for each study. The consent form must be appropriate in length and content to the characteristics of each study.** The consent form must address the potential research participant directly (“You are invited ...”) with language appropriate to the age and reading level of the intended participant. The style must be simple, avoiding or explaining in lay terms scientific or medical words or expressions. Legalistic phrases or expressions are also to be avoided so the consent form does not read like a contract.

Suggested wording for each section is provided in text boxes. Researchers are free to cut and paste keeping in mind the text should be adapted to the specificity of the study.

[Institutional logo/letterhead]

PARTICIPANT INFORMATION AND CONSENT FORM

The heading “Participant Information and Consent Form” should specify, if necessary, to whom it is directed (participant, control, parent, sibling, etc.).

Title of Study

- Should convey that the proposed intervention is for research rather than for educational, treatment, or other purposes.
- Must be the exact title of the research protocol. A short, simplified title may accompany the title if it is too difficult for a layperson to understand.
- If more than one consent form is required, each consent form should be titled appropriately (e.g., consent forms for tissue/blood banking, pharmacokinetic studies).

Principal Investigator

- Name, Institution and Contact Information

Sub-Investigator(s)

- Name and Institution

Sub-investigators may not need to be listed if they have little or no contact with study participants (e.g. for referrals, or doing laboratory tests).

Student(s) Researchers

- If the researcher is a student, this must be explicitly stated and the supervisor clearly identified.

Sponsor

- Name(s) of industry sponsor or granting agency (as applicable)

Emergency Telephone Number

- A 24-hour, 7-day a week phone number is required for studies that are more than minimal risks to research participants from participation.

INTRODUCTION

The introduction is required for all studies. It is the invitation to participate. The reason to invite these particular individuals should be stated by describing characteristics of the sample population that are important for the study. The introduction also stresses the voluntary nature of participation and the right to withdraw at any time.

<p><i>Suggested Wording</i> You are invited to take part in this research study because you</p> <p>Your participation is voluntary. It is up to you to decide whether or not you wish to take part. If you decide to participate, 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 affect your {care, employment or academic standing, as applicable}.</p> <p>Please take time to read the following information carefully. You can ask the study doctor or staff to explain any 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.</p>

WHO IS CONDUCTING THE STUDY?

This section is required for all studies. It is used to name all agencies contributing funds {including grants-in-aid}, resources, drugs, and other products to the study.

This section is also used to declare any other actual or potential conflicts of interest for conducting or being involved with any part of the study. For instance, the possibility of

commercialization of research findings that may benefit the local institution and / or researchers should be mentioned, when applicable.

Suggested wording

Scenario #1

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

Scenario #2

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.

WHY IS THIS STUDY BEING DONE?

This section is required for all studies. It provides a brief explanation why the research is being done. A participant should understand clearly why a particular health problem/intervention needs to be studied. For example, this can include non-technical information on the incidence of a disease, on the problems associated with a disease, on the poor outcomes for other treatment methods, etc. It should indicate if the study is “observational” (e.g. collection of clinical data or other information in a unique population) or “experimental” (how does it differ from standard care – e.g. new drug, dietary or herbal supplement, new formulation of an approved drug, different doses than commonly used, new device, new order of treatments for a particular condition, as applicable).

Key points to include in this section, when applicable:

- clearly explain what the standard treatment(s) is/are and what basis exists for the experimental intervention;
- indicate if the research is being carried out for the first time in humans;
- indicate if the research is part of a larger multi-site clinical trial;
- indicate the number of participants to be recruited at the local site.

Suggested wording

This study is being done because ... *{add brief explanation of the research question }*.

WHO CAN PARTICIPATE IN THE STUDY?

This section is not required in most studies. It is used to specify the inclusion and exclusion criteria for the study. **It is the investigator’s responsibility (and not the research participant’s) to ensure that research participants fit the inclusion and exclusion criteria for research studies.** However, exclusion criteria which participants are likely to recognize (e.g. allergies, exposure to infectious conditions) can be listed, using lay terms (i.e., do not use diagnostic classes or technical language) if they provide an additional safeguard to participants from being inappropriately enrolled in research where they have personal health-related information, which may not be available to the investigators, and which could pose a significant risk or mitigate possible benefits from participation.

Suggested wording

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

Or

You should not/may not participate in this study if*{add a brief description of the exclusion criteria}*

WHAT DOES THE STUDY INVOLVE?

This section is required for all studies. The first paragraph is used to describe briefly in lay language the overall design of the study. This paragraph should include some or all of the following information, as applicable:

- a. Indicate any specific tests required to determine eligibility (e.g. biopsy results, psychological tests, blood, tissue or urine analysis).
- b. Describe the study groups and how participants will be assigned to the study groups (e.g. “You will be assigned randomly by a computer to group A or B”).
- c. If the study is “double-blinded”, explain that neither the research participant nor the study doctor will know which treatment the research participant is receiving, but that information will be made available in the event of a medical emergency.
- d. Indicate the time requirement for each study visits.
- e. Indicate if study participation involves withholding of standard treatment before (wash-out period) and/or during the study. Provide justification to the research participant for the withholding of standard treatment. Indicate availability of “rescue medication”, as applicable.
- f. Indicate if the study includes a placebo arm. Please note that Article 7.4 of the TCPS indicates that the use of placebo controls in clinical trials is generally unacceptable when standard therapies or interventions are available for a particular patient population. For more details of circumstances in which a placebo may be used in a clinical study, consult the TCPS, section 7.4. If the test article is compared to placebo, the consent form must inform the potential participant about:
 - i. any therapy that may be withheld or withdrawn for the purposes of the study;
 - ii. the possible consequences of withholding or withdrawing this therapy;
 - iii. the reasons why the use of the placebo is considered necessary;
 - iv. the chance of being assigned to the placebo arm of the study;
 - v. the availability of “rescue medication”;
 - vi. the right to withdraw should the research participant feel his/her condition is worsening.

The **next paragraphs** must describe **ALL** research-related procedures including those that may be required before the experimental intervention is initiated. The explanations should be such that participants will be able to comprehend the extent of their involvement in the research study, as well as be able to understand each step of their participation. **In particular, the experimental procedures that are beyond standard care should be clearly laid out.** These may include standard or common investigations, which would not normally be done in routine clinical care for the particular problem being investigated, or which are done more frequently during the research than in routine clinical care for that particular problem.

It is often useful to divide the study in its various phases such as:

- i) Initial Visit/Before You Begin the Study/Screening Visit
- ii) Randomization Visit

- iii) Study Visits - These can be described in a variety of ways depending on the research procedures (e.g., Day 1, 2, 3; During the First Year of Your Participation in the Study, During the Remaining Years of Participation in the Study; First/Second/Third Visit; For Participants in Group 1/Group 2).
- iv) Expected Follow-up - Describe the number of follow-up visits and their duration.

Blood/Tissue collection

If blood, body fluids and tissue samples are collected, the consent form must include all of the requirements of TCPS 10.2. The consent form must indicate what will be done with these samples as part of the study and with any remaining samples upon completion of the study.

If blood testing is involved, indicate the amount of blood to be taken in mL, followed by lay terms (e.g. “teaspoons (≈5mL) or tablespoons (≈15mL), or equivalent to a standard blood donation”) and the purpose of the blood sampling.

Mandatory tissue banking is only permitted if the tissue is being banked for purposes directly related to the study at hand (i.e. the tissue banking must be integral to the study, such that there would be no study if the participant did not contribute the tissue). It is unethical to require that participants agree to allow their tissue to be banked for future use or experimentation that is unspecified or unrelated to the study at hand as a condition for entry into a therapeutic trial, as this could be perceived as a coercive method of obtaining tissue/blood samples through offering a perceived therapeutic opportunity.

Participants may voluntarily donate their tissue for future, unspecified uses provided that the following conditions are made explicit in the main consent form for the study: a) that such donation is optional, and b) that the Investigator discloses whether or not they plan to seek the participants' consent for future projects involving their tissue.

Medical Scans

If medical scans with radiation are required, indicate the level of radiation to which the participant is exposed in a way that a participant can understand (e.g. compared to standard procedures such a chest x-ray). A section under “Risks and Discomforts” should indicate the risks associated with medical scans, as appropriate.

Interview / Questionnaires

If the research study includes interviews or questionnaires, describe the general purpose of the questionnaires (e.g. participant's health status, functional status, quality of life, etc.). Add a note that the participant may refuse to answer questions he/she is not comfortable with.

For interview(s)/questionnaire(s) that may be upsetting to the respondent (i.e. induce embarrassment, humiliation, lowered self-esteem, guilt, conflict, anger, distress or any other negative emotional state), include referrals for counseling and other services, where appropriate.

Health Records and use of data from secondary sources

The consent form should indicate if the participant's health record will be reviewed or excerpts extracted from it. If data is collected from secondary data sources, the consent form must include all of the requirements of TCPS 3.2.

For studies accessing records maintained by the Saskatchewan Ministry of Health, the consent must explicitly make reference to:

- why the information is required from the Ministry of Health
- which services the individual is providing consent for the Ministry to release (e.g., doctor visits, prescription drug information)
- the type of information which would be included on those services (e.g., date of a visit, the diagnosis, type of service provided (e.g., annual physical examination), type of physician (e.g., family doctor or a specialist), etc.)
- the time period over which the services were received (e.g., specify which years or the number of months/years before or after a certain time such as the date the survey is being conducted)
- their health services number and health care records remaining confidential

Optional Sub-Studies

A separate section should be used to describe any studies that are not part of the main study and for which separate consent must be obtained, for example, tissue and blood banking studies; pharmacokinetic studies, analysis of secondary data from linked databases.

Optional sub-studies involving tissue banking and genetic testing are best presented in a separate consent form. Requiring a separate information and consent for genetic testing better assures particular regard for the privacy and confidentiality issues that genetic testing may warrant. Nesting all of the information relevant to genetic testing within a larger protocol and consent form tends to reduce a research participant's particular attention to these matters.

Suggested wording

Even if you choose to take part in this study, the following sub-study is optional. This optional study is for...*{define purpose of sub-study}*. It requires...*{define requirements such as additional blood draws or questionnaires}*. You can take part in the main study and not take part in the optional sub-study. You can indicate your wish on the last page of this form or by signing a separate consent form *[as applicable]*.

WHAT ARE MY RESPONSIBILITIES?

This section is not required for all studies. It is used to list and specify any requirements of the study that the participant must comply with in order to participate. For instance, requests to complete a daily diary, to report any changes in health or to contact their study doctor before taking any medication, natural products or herbal remedies other than the study drug could be listed here.

Suggested wording

As a study participant, you will be expected to:

- Follow the directions of the Principal Investigator
- Report all medications being taken or that you plan on taking
- Report any changes in your health to the Principal Investigator
- [List other participant responsibilities, such as birth control or pregnancy reporting requirements for both male and female participants and partners, as applicable]

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

This section is required for all studies. It is used to identify benefits to participant, if any. This information should include relevant information about the nature of the potential benefits, stated in an even-handed manner, with both excessive pessimism and undue optimism to be avoided. Alternatively, it should also be mentioned if no direct benefit to participants is anticipated.

If medical treatment is involved, a statement should be added that beneficial effects cannot be guaranteed. Financial compensation and medical tests at no cost to the participant are NOT considered benefits of participation in the study and should not be included in this section.

In research projects where there may be anticipated benefits to society or to a specific group, these potential benefits may be explained in a separate sentence / paragraph so as not to confuse potential benefits to others with potential benefits to the research participant.

In some studies, clarify whether or not the investigators can / will provide the participant with the results from the study, which in some cases may be considered a benefit.

Suggested wording

If you choose to participate in this study, there ... *{may/will or may/will 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.

The study may lead to the development of commercial products but there are no plans to share with you any financial profits resulting from the use of your samples or data.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

This section is required for all studies that pose more than minimal risk to a research participant. It is usually best to describe the risks of each procedure in a separate point. Risks should be arranged and described according to their severity and the likelihood/probability of their occurrence. It is helpful to divide risks quantitatively (e.g. rare, less than 1%; common, 1-10%; very common 10-upper %), according to severity and likelihood of occurrence. Excessive use of charts with statistics should be avoided if such use leads to difficulties in the recognition of the main risks associated with the study. References to animal studies are usually omitted unless there is a serious risk likely relevant to humans that is identified. If there is little experience with a new drug or treatment, it is important to state this and that unexpected side-effects may occur. If there is no known risk, a statement may be added to that effect as reassurance to a potential research participant. Where appropriate, it should be indicated how a particular side-effect may be recognized, what precautions will be taken to avoid certain side effects and what will be done should they occur.

Suggested wording

While on the study treatment, you may experience side effects. There may be side effects that are not known at this time. Most side effects go away when you stop taking the study drug. Others may be long-lasting or permanent.

Up to now, there has been *{number}* of people exposed to the study drug.

The following side effects are very common, occurring in *10-[insert upper %]* of people taking the drug: *{list}*

The following side effects are common, occurring in *1-10%* of people taking the drug: *{list}*

The following side-effects are rare, occurring in *less than 1%* of people taking the drug: *{list}*

Placebo risk (if applicable)

In the case of a placebo-controlled study, the chance of being assigned to the placebo arm of the study should be stated along with the possible consequences of withholding therapy for a particular condition. The right to withdraw from the study should a participant's condition worsen should be clearly stated.

Suggested wording

You have {probability} of being assigned to the group receiving a placebo. A placebo looks identical to the study drug / device but contains no active ingredients. If you or your study doctor feels your condition is getting worse than expected, you may be withdrawn from the study and offered appropriate care.

Reproductive risks (if applicable)

There must be special attention paid to a study medication or treatment that may pose a risk to developing fetuses or to babies who are being breastfed. Any birth control requirements (specify type of birth control) or pregnancy reporting requirements should be listed in this section for both male and female participants (and partner). What will happen in the event of a pregnancy (withdrawal from the study and with the participant's permission, follow-up) should be described. In the event of a pregnant partner of a research participant, the request for follow-up should be "with permission". It should be indicated if a separate consent form will be used to request the pregnancy follow-up.

Suggested wording

The medication or treatment used in this study may pose a risk to a developing fetus or a baby who is being breastfed. If you are a sexually active woman capable of becoming pregnant (sexually mature woman who has not undergone a hysterectomy or who has not been post-menopausal for 24 consecutive months), you must use a medically approved effective method of birth control, or you must not have sexual intercourse that could result in pregnancy while on {name of drug or treatment} and for {xxx months} after stopping it. Acceptable methods of birth control are {...list}. Women who are breastfeeding are not eligible to participate in this study.

If you are a man and capable of fathering a child, you must use acceptable methods of birth control every time you have sexual intercourse with a female partner, or you must not have sexual intercourse that could result in pregnancy while on {name of drug or treatment} and for {xxx months} after stopping it.

If you or your partner becomes pregnant while participating in this study, it is important that you notify the study doctor immediately. If you are a female participant, you will be withdrawn from the study. The study doctor will ask your permission (or that of your pregnant partner) to follow the progression and outcome of the pregnancy.

WHAT ARE THE ALTERNATIVES TO THE STUDY TREATMENT?

This section is not required for all studies. When the research includes patients as participants, it is important that the prospective research participant know whether or not there are any alternatives (i.e., other standard treatments) to the treatment that they would receive in the study. If there are alternative therapies, they should be listed, with a note that they will be discussed with the study doctor. If there are no alternative therapies, this should be stated. If the prospective participants are suffering from a terminal illness, and there are no alternative treatments available, the option of supportive care or comfort control measures should be included.

Suggested wording

You do not have to participate in this study to receive treatment for your condition. If you choose not to participate in this study, the following treatment options are available to you: {list them}. Your study doctor will discuss these options with you, including the risks and benefits of each option.

WHAT IF NEW INFORMATION BECOMES AVAILABLE?

This section is not required for all studies. During the research study, participants must be given continuing and meaningful opportunities for deciding whether or not to continue participation. Participants should be told that if new information arises during their participation that may affect their willingness to remain in the study, they will be advised of this information. For example, participants would need to be advised if a more effective treatment became available, or if new risks had been identified in relation to their participation in the study.

Suggested wording

During the course of this study, new information that may affect your willingness to continue to participate will be provided to you by the investigator. This includes information about newer, more effective treatments that might become available or any significant change in the risks you are exposed to from your participation in this study.

WHAT HAPPENS IF I DECIDE TO WITHDRAW?

This section is required for all studies. It should explain that the participant can stop participating at any time without penalty. It should also be indicated that the participant does not have to provide any explanation for doing so.

The following information should also be included in this section when applicable:

- If gradual withdrawal is required for safety considerations, explain this and any unique procedure required for timely and safe withdrawal;
- Explain that examinations (physical, blood pressure, blood tests, etc.) may be recommended for safety reasons if the participant decides to withdraw from the study and that these would occur after the participant has been released from the study, with permission of the participant;
- Explain that the investigator will retain any data collected up to the point of the participant's withdrawal from the study, such that the data itself cannot be withdrawn;
- For participants in double-blind studies, explain whether participants will be able to find out what treatment they were receiving.
- In studies where it is not possible to undo the research-related intervention (e.g. somatic cell gene transfer or implantation of medical device) this must be disclosed. However, the participant can withdraw from participation in the research (e.g. the ongoing evaluation) even though the procedures performed cannot be undone.

Suggested wording

Your participation in this research is voluntary. You may withdraw from this study at any time. You do not have to provide a reason. Your future medical care *{for employment or academic status, as applicable}* will not be affected.

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

CAN I BE ASKED TO LEAVE THE STUDY?

This section is not required for all studies. It is used to describe under what circumstances the study investigator would take the participant out of the study. For example, the study may be stopped by the sponsor or regulatory agency if knowledge of any unexpected or unexplained serious adverse events that affect participant safety becomes known, the participant needs treatment not allowed in the study, the participant does not follow instructions, became pregnant, or a better treatment has become available.

Suggested wording

The study doctor may decide to discontinue the study at any time, or withdraw you from the study at any time if it is felt to be in your best interests. You may be withdrawn from the study if staying in the study would be harmful, you need treatment not allowed in the study, you fail to follow instructions, you become pregnant, or the study is cancelled by the sponsor for administrative or other reasons.

WHAT HAPPENS IF SOMETHING GOES WRONG?

This section is required for all studies in which there is potential harm to the research participant from participation.

There are three essential statements in this section:

- That in the event of an adverse event, the research participant seeks immediate medical attention.
- That medical attention will be provided at no cost to the research participant.
- That the research participant is not waiving any legal rights to seek compensation for damages by signing the consent form.

Statements concerning availability (or absence) of compensation from the Sponsor for research-related injuries are acceptable, so long as they provide information which may help the potential research participant decide about his/her participation in a research study. Statements off-loading the costs of research-related injuries onto a third party (e.g. the provincial health care plan), are not acceptable without permission of that third party. Neither the REB nor the sponsor can speak on behalf of the Saskatchewan Ministry of Health as to what may (or may not) be covered in the event of a research-related injury.

Suggested wording

Scenario #1

In the case of a medical emergency related to the study, you should seek immediate care and, as soon as possible, notify the study doctor. Inform the medical staff you are participating in a clinical study. Necessary medical treatment will be made available at no cost to you. By signing this document, you do not waive any of your legal rights against the sponsor, investigators or anyone else.

Scenario #2

“In the case of a medical emergency related to the study, you should seek immediate care and, as soon as possible, notify the study doctor. Inform the medical staff you are participating in a clinical study. Necessary medical treatment will be provided. Compensation for other things such as loss of time and income is not provided. By signing this document, you do not waive any of your legal rights against the sponsor, investigators or anyone else.”

Scenario #3

In the case of a medical emergency related to the study, you should seek immediate care and, as soon as possible, notify the study doctor. Inform the medical staff you are participating in a clinical study. *{Sponsor}* will pay the medical expenses for any study related injury directly attributable to the trial procedures or the study medications properly administered, as long as you have followed the directions of the doctors in charge of the study. If you are unsure about your ability to follow these instructions, discuss it with the study doctor or a member of the study staff without delay. By signing this document, you do not waive any of your legal rights against the sponsor, investigators or anyone else.

WHAT HAPPENS AFTER COMPLETION OF THE STUDY?

This section is used to provide any information that may be useful to the participant once their participation is concluded. For example, this could include whether or not a participant will be able to continue treatment on the study drug. Availability of the study drug through an extension study or through the Special Access Program may be stated here. If the study drug will not be available after the study ends, some explanations should be provided, with a statement that treatment options will be discussed with the study doctor.

If practical, researchers should also inform participants if/when study results are likely to be available and how to access them. With industry-sponsored research involving study centers worldwide, the results may not be available for several years after the participant his/her participation in the study.

Suggested wording

You {will/may/may not} be able to receive the study treatment after your participation in the study is completed. *{Specify reasons or options, as applicable}* The study doctor will discuss all future treatment options with you at the end of the study.

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

WHAT WILL THE STUDY COST ME?

This section is required for all studies and is used to stipulate that a research participant will not be charged for study drugs or procedures. This section should stipulate whether or not the participant will incur any personal expenses (e.g., parking, meal, etc.) as a result of participation and whether or not these will be reimbursed. If an honorarium is to be paid (instead of reimbursement for specific expenses), the total dollar amount should be specified, as long as it is not large enough to constitute an “inducement”. The honorarium should be presented in the sense

that participants are being reimbursed for their time, travel expenses, and the inconvenience of being a research participant. Participants who withdraw early may not be penalized for doing so and must receive compensation proportionate to their time in the study.

Suggested wording

Scenario #1 – No reimbursement for expenses provided

You will not be charged for the study drug(s) or any research-related procedures. You will not be paid for participating in this study. Reimbursement for study-related expenses (e.g. travel, parking, meals) is not available.”

Scenario #2 – Reimbursement for study-related expenses provided

You will not be charged for the study drug(s) or any research-related procedures. You will not be paid for participating in this study. Reasonable expenses for study visits may be reimbursed if they are first discussed and approved by the Study Doctor before the costs are incurred.

Scenario #3 – Fixed Honorarium provided to cover study-related expenses

You will not be charged for the study drug(s) or 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.

WILL MY PARTICIPATION BE KEPT CONFIDENTIAL?

This section is required for all studies. It is used to remind a research participant of his/her privacy rights and to disclose where, how and for how long the information collected will be kept. There are two main concerns: **anonymity** (how will the investigator prevent identification of participants in a study) and **confidentiality** (what steps are taken by the researchers to safeguard access to the information collected). This section should also be used to inform the research participant if their family physician should/will be informed of participation in the study.

If and how the information will be de-identified should be clearly stated (e.g. use of unique study code and/or scrambled initials). For all statements regarding confidentiality of research records, it should be kept in mind that there is no legal privilege between investigator and participant as there is between physician and patient or counselor and client. Thus, a guarantee of complete confidentiality, or "strictest confidentiality," should not be given or implied. In rare instances it will not be possible to ensure confidentiality because of mandatory reporting of reported child abuse, communicable diseases, etc. When this is the case, the participants should be made aware of this limitation in the consent form.

Suggested wording

Scenario #1

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. Your name will not be attached to any information, nor mentioned in any study report, nor be made available to anyone except the research team. It is the intention of the research team to publish results of this research in scientific journals and to present the findings at related conferences and workshops, but your identity will not be revealed.

Scenario #2

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.

Your study records will be identified by *{indicate de-identification protocol}*. They will be kept for *{XX years}* in a secure area such as a locked file cabinet and office *{at research center}*. Tissue samples and results of the study without your name or other information that could identify you will be sent to *{sponsor and ...}* and combined with information from other participants for analysis.

No information that discloses your identity will be released or published without your specific consent. Some authorities have a duty to check your study and medical records to make sure all the information is correct. Your study and medical records may be inspected in the presence of the investigator or his/her qualified designate by representatives of (insert here, if relevant to study- the study sponsor, Health Canada, the U.S. Food and Drug Administration and the *{institutional}* Research Ethics Board).

If you decide to withdraw from this study, your study and medical records will be made available to these agencies. However, they will only look at your records up to the date of your withdrawal, except where the reporting of side effects associated with the study medication is required. Rarely, your study documents may be obtained by courts of law. You may ask the study doctor to see and copy your personal health information related to the study. You may also ask the study doctor to correct any study related information about you that is wrong. In the case of a blinded study, you may have to wait until the end of the study to see your study records to protect the integrity of the study.

The results of this study may be presented in a scientific meeting or published, but your identity will not be disclosed.

For your own safety, it is strongly recommended that your family physician be informed of your participation in this study. With your permission, he/she will be informed and may be consulted regarding your health and treatment.

For studies that in the researcher's judgment pose significant health risks to the participant, the requirement to inform the family physician may be mandatory, but the participant must be informed of this requirement.

Suggested wording:

For your safety, your family physician will be informed of your participation in this study and may be consulted regarding your health and treatment.

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

This section is required for all studies. It is used to provide contact information for the Principal Investigator for questions about the study and to the Research Ethics Board for questions concerning the participant's rights and experiences as a research participant.

Suggested wording

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 Saskatchewan Research Ethics Board, at 306-966-2975(out of town calls 1-888-966-2975). The Research Ethics Board is a group of individuals (scientists, physicians, ethicists, lawyers 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 Saskatchewan Research Ethics Board.

Required wording:

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

PARTICIPANT CONSENT TO PARTICIPATE

This section is required for all studies. The participant is signing the form to indicate that he/she has either read (or otherwise been informed), and understands the information concerning the study. The first person pronoun (“I”) is used for this section. Contractual-sounding language should be avoided and it should be clear that the participant does not give up any legal rights by signing it.

In cases of minors or individuals with cognitive handicaps unable to provide consent, the TCPS places certain conditions on when these individuals can be invited to participate in research (see articles 2.5, 2.6, 2.7 and 5.3). If these conditions are met, it should be determined whether a parent, guardian, or other representative has the legal authority to give consent to the proposed research, and if so, that individual’s consent must be obtained. An assent form in appropriate language for minors or adults without capacity should also be used, when applicable. If not, the form should indicate that assent from the participant has been obtained even if the parent/proxy has consented. A means of recording that assent was obtained (signature line with yes/no checkboxes) should be included in the consent form, if an assent is not used. Individuals, who verbally or behaviourally indicate that they do not wish to participate, must be allowed to withdraw even when proxy consent has been given. If a participant becomes able to consent on his or her own behalf during the course of the study, this consent must be obtained in order for the participant’s participation to continue.

There is no clear basis in Saskatchewan law for a “legally authorized representative” to make decisions for a non-competent individual for research purposes. It is the researcher’s responsibility to ensure that the person providing consent has the authority to do so. It is suggested that the “authorized representative” be defined, for example:

“An authorized representative in this study is the person who has the authority to make a decision about participation in the study on behalf of a participant who does not have the capacity to decide, as the participant’s parent or guardian or as someone who was entrusted by the participant to make such decision when the participant was competent. The authorized representative should decisions according to the participant’s wishes and best interests.”

If the consent form is being translated verbally for the research participant, then the translator must also sign the consent form indicating that the translation was to the best of his/her ability.

The signature of a witness is optional. It is not required by law but is recommended by the International Conference on Harmonization (ICH) / WHO Good Clinical Practice standards (ICH-GCP).

A copy of the signed and dated consent form must be given to the participant.

Suggested wording

CONSENT TO PARTICIPATE

- 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 have been informed of the other treatments available for my condition.
- I was given sufficient time to think about it.
- I had the opportunity to ask questions and have received satisfactory answers.
- 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 medical care.
- I agree to follow the study doctor's instructions and will tell the study doctor at once if I feel I have had any unexpected or unusual symptoms.
- I have been informed there is no guarantee that this study will provide any benefits to me.
- I give permission for the use and disclosure of my de-identified personal health 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 and dated copy of this consent form.

- *(If applicable)* I agree to participate in the optional sub-study on *{define}* Yes No

- My family physician can [or will] be informed about my participation in this study, and, if required, consulted regarding my health and treatment.
 - Yes, you may contact my primary care physician
 - No, please do not contact my primary care physician
 - I do not have a primary care physician.

- *(If applicable)* I grant the Saskatchewan Ministry of Health permission to disclose my health care information to the study researchers Yes No

I agree to participate in this study:

Printed name of participant:

Signature

Date

Printed name of person obtaining consent:

Signature

Date