Preparing a Consent Form

The consent form is one aspect of a process meant to inform an individual about a research project they may be interested in and eligible for. Consent is an ongoing process that continues throughout the research. It begins with the initial contact (e.g., recruitment) and carries through to the end of the participant's involvement in the project.

The consent form has the following objectives:

1. It is an **information tool**. It should be 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. The consent form may cause the participant to ask questions, which the researchers will be responsible for answering.
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 to, and retention in, a research project in such manner 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 essential information that must be communicated to a potential research participant and how to communicate that information.

General Principles of consent (TCPS 2 (2022) Chapter 3)**:**

1. Consent shall be given voluntarily
2. Consent shall be informed
3. Consent shall be an ongoing process
4. Consent shall precede collection of, or access to, research data
5. Consent shall be documented

The following document provides a step-by-step description of each element of a consent form and why it is required. **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. A general rule of thumb is for the content of the consent form to be at a grade 8 reading level. It is important to include page numbers {e.g., 1 of 8} and a version number on the footer.

There is considerable diversity in how individuals and groups understand, experience, and express gender. Please ensure the consent form is written in gender-inclusive language. Consider referencing the resources available through the Tri-Agencies on how to account for sex and gender in research.

For ease of use, and due to the difficulty of tailoring consent forms to groups with varying degrees of maturity or capacity (for example, children), it is suggested that this consent form template be used for both parent/legal guardian/authorized representative consent and assent.

Suggested wording for each section is provided in text boxes. Researchers are free to use the suggested wording, 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, caregiver, 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 should be listed if they will have study-specific contact with the participants (e.g., for referrals, or doing laboratory tests).

Student Investigator(s)

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

Sponsor

- Name(s) of industry sponsor or granting agency (as applicable). (Note: A sponsor takes responsibility for the initiation and management of research and compliance with applicable regulations. The sponsor may or may not be the main funding organization)

For unfunded projects, consider listing the institution i.e. The University of Saskatchewan

Emergency Telephone Number

- A 24-hour, 7-day a week phone number is required for studies that are above minimal risk. The person that will be reached at the number should be indicated. If the number is for a switchboard, identify the person that should be paged (e.g., specialist on call, PI, etc.)

For minors or individuals who lack capacity, include the following wording:

If you are the parent, legal guardian, or authorized representative of an individual being invited to take part in this study, permission from you may be required. The words "you" and "your" always refer to the participant in the study.

For e-consenting, include the following:

This study uses an e-consenting process. This means that you will receive an electronic copy of the consent form and if you agree to participate, will be asked to provide your signature electronically. The option to provide wet-ink (paper) signatures is also available to you, if preferred or required.

INTRODUCTION

An 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 (i.e., inclusion criteria) that are important for the study. The introduction also stresses the voluntary nature of participation and the right to withdraw at any time.

Suggested Wording

You are invited to take part in this research study because you …{*fill in relevant information that explains why the person may potentially qualify for the study.*}

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 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, institution, or other affiliations as applicable}.

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.

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 real, potential, or perceived 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 of 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 of 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). If the device or therapeutic agent is new or used in a manner not

specified in its most recent product monograph, a statement indicating that Health Canada has approved the use of the device or therapeutic agent for the specified uses described in this consent must be included.

Key points to include in this section, when applicable:

- Clearly explain the standard treatment(s) and the basis 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 project;
- 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? (Optional, if relevant to the participant)
This section is not required for most studies. It is used to specify the inclusion and exclusion criteria for the study. The determination of inclusion and exclusion criteria affects the fair and equitable distribution of the burdens and benefits of research. The focus, objective, nature of research, and context in which the research is conducted, inform the inclusion and exclusion criteria for a specific research project. **It is the investigator's responsibility (and <u>not</u> the research participant's) to ensure that research participants fit the inclusion and exclusion criteria for research studies.** However, there may be exclusion criteria that are likely to be recognized by the participant, that are not necessarily available to the investigators (e.g., allergies, exposure to infectious conditions). Making the participants aware of these could provide an additional safeguard to ensure that participants are not inappropriately enrolled in research that could pose a significant risk or mitigate the possible benefits from participation.

Suggested wording
You are eligible to participate in this study if …. *{add a brief description of the inclusion criteria}*
and/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 briefly describe the overall design of the study in lay language. This paragraph should include 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. Ensure lay language is used here. For example: "We will use a computer to assign you to one of the study groups. This process is called "randomization." It means that your doctor will not choose, and you cannot choose which study group you are in. You will be put into a group by chance".
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 visit and the study location(s).
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 11.4 of the TCPS 2 (2022) 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 2, Article 11.4. If the new therapy or intervention is compared to a 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 their 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 of 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 into its various phases/visits 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/or tissue samples are collected, the consent form must include all of the requirements of TCPS 2 (2022) Chapter 12. The consent form must indicate what will be done with the 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 collection is only permitted for purposes directly related to the study at hand (i.e. the tissue collection 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 stored 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. The length of time for retaining biological materials for study purposes must be stated as per TCPS 2, Article 12.2 provides additional guidance on information that prospective participants generally require to make an informed decision to donate biological materials for use in research (i.e., commercialization, withdrawal limitations).

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 as dental x-rays/international flights). A section under "Risks and Discomforts" should indicate the risks associated with medical scans, as appropriate.

Interviews/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 choose not to answer questions they are 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. If the interview(s)/questionnaire(s) are completed online, identify the website survey platform, and provide a brief description of the data privacy policy, including the location where the data is stored, and provide a link to the platform's privacy policy. E.g., "This survey is hosted by Survey Monkey. Your data will be stored in facilities hosted in Canada. Please see the following for more information on the Survey Monkey Privacy Policy."

Provide information on how the responses will be documented and/or recorded and outline any limitations to the privacy and confidentiality of their data with the methods being adopted. Describe any audio or video recording devices being used and explain what happens to the recordings after they have been transcribed (i.e., deleted from the recording device). Include a statement to indicate that participants may request that the recorder be turned off at any time without giving a reason.

Describe if a transcript review is part of your procedure, e.g.: *"*After your interview, and prior to the data being included in the final report, you will be given the opportunity to review the transcript of your interview, and to add, alter, or delete information from the transcript as you see fit." Be sure to include a deadline for the return of revisions to you and a description of what will happen if the deadline is missed. Identify who will transcribe any recordings of the interview and state that they will sign a confidentiality agreement, if a third party.

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 the requirements of TCPS 2 (2022) Article 3.2. (Consent Shall Be Informed).

For studies accessing records maintained by the Saskatchewan Health Authority, operational approval must be sought, and the consent form must explicitly refer to:

- Why the information is required from the Saskatchewan Health Authority;
- Which services the individual is providing consent for the Saskatchewan Health Authority 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);
- How their health services number and health records will remain 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 explicit consent must be obtained; for example: tissue and blood banking studies, pharmacokinetic studies, and analysis of secondary data from linked databases. For example, participants may consent to 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.

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]*.

If you choose to take part in this optional study *{insert specimen to be collected. E.g., a sample from your previous biopsy}* will be collected and stored. Storing samples for future studies is called "biobanking." The biobank is being run by *(insert name)* in *(insert location of biobank- at least country)*. Also, any health-related information, such as your response to cancer treatment, results of study tests, and medicines you took, will be stored for future use.

We will protect your privacy. The goal of biobanking is to make more research possible that may improve people's health. The biobank has controlled access. This means that researchers who want to get samples and data from it must submit a specific research request. The request identifies who they are and what their planned research project is. Before getting the samples and data, the researchers must agree to keep the data private, only use it for their planned research project, and never use it to try to identify you.

Right now, we don't know what research may be done in the future using your *(blood and/or tissue)* samples. This means that:
You will not be asked if you agree to take part in the future research studies.
You and your study doctor will not be told when or what type of research will be done.
You will not get reports or other information about any research that is done using your samples.

WHAT ARE MY RESPONSIBILITIES? (If applicable)

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

If you choose to take part in this study you will need to:
- Keep your study appointments.

- *For studies using non-marketed drugs or other investigational interventions, include as appropriate:* Make every effort to return to the clinic/hospital where the study drug was given if you experience serious side effects that require treatment.
- Tell your study doctor about:
  - all medications (prescription and non-prescription) and supplements you are taking, including vitamins and herbals, and check with your study doctor before starting, stopping, or changing any of these. This is for your safety as these may interact with the treatment you receive on this study;
  - any side effects;
  - any doctors' visits or hospital stays outside of this study;
  - if you have been or are currently in another research study, or are thinking about participating in another study.
- *(Include as appropriate)* Return any unused study medication, and completed diaries and questionnaires.
- *(Include as appropriate)* Write down in your medication diary when you take the study drug at home.
- *(Include as appropriate)* Avoid eating/drinking *(specify what/for how long).*

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 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, medical tests conducted at no cost to the participant, more frequent testing, or close monitoring 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 the investigators can/will provide the participant with their individual 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/may not/ 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. *{if applicable, add a list of any potential benefits that participants may receive because of their participation}*

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. {*if applicable*}

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

This section is required for all studies. Risks of each procedure, treatment, or drug should be described 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, by the Council for International Organizations of Medical Sciences guidelines (e.g., very common >10%), common (1 – 10%), uncommon (0.1 – 1%), rare (0.01 – 0.1%), very rare <0.01%)) 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

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 and explain how researchers plan to mitigate those risks}*

Example for drug study: 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 have been *{number}* of people exposed to the study drug.
The following side effects are: List categories {very common, common, uncommon, rare, and very rare, as applicable}

If e-consenting is used: If you choose to provide your signature electronically, you will receive the consent form through a secured email from the research team. There are inherent risks involved with sending information electronically, especially when using public devices and personal email accounts. Please follow common security measures to protect your personal information and feel free to discuss this with the study team if you require more information.

Risk of using a placebo as a comparator **(if justified based on TCPS 2 (2022) Article 11.4)**

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 possibility that the participant's condition could worsen. The participant also needs to be informed that they can choose to withdraw from the study at any time or the study doctor could decide to have them withdrawn if it is in the best interest of the participant. (This is true regardless of what arm they are assigned to).

Suggested wording

You have {probability} of being assigned to the group receiving a placebo and not the standard medication for your condition. 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 will be 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(s)). 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 that a separate consent form will be used to request the pregnancy follow-up.

Suggested wording
Use and adapt the following text for all studies as required by the protocol, and include additional detail as required.
The *{specify intervention}* used in this study could be very harmful to an unborn or newborn baby. There may be some risks that doctors do not yet know about. It is very important that you check with your study doctor about methods to prevent pregnancy to use during the study and for *{insert time in months/years}* after you have completed the study (*or the last dose)*.

WHAT ARE THE ALTERNATIVES TO THE STUDY TREATMENT? (If applicable)
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 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? (If applicable)
This section is not required for all studies. During the research study, participants must be given continuing and meaningful opportunities for deciding whether 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 study doctor {*or researcher*}. 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 indicate 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 whether the participant can request their data or samples be withdrawn from the study and outline any reason why full withdrawal might not be possible. For example: when the data is pooled and/or analyzed it may not be possible to have the data and samples removed; or if the samples have been used or analyzed, data from the analysis cannot be withdrawn or destroyed even if the samples are.
- For participants in double-blind studies, explain whether participants will be able to find out what treatment they were receiving and estimated timeline.
- 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 *{or 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? (If applicable)
This section is not required for all studies. It is used to describe under what circumstances the study investigator would need to discontinue an individual's participation in a 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, the participant becomes pregnant (where this is an exclusion criterion), or a better treatment has become available.

Suggested wording
The study doctor may take you off the study if:
- Your health changes, and the study is no longer in your best interest, or you are unable to tolerate the study treatment.
- New information becomes available, and the study is no longer in your best interest.
- You are unable to complete all required study procedures.
- *(Include as appropriate.)* For females: You become pregnant while on the study.
- *(Include as appropriate.)* If your treatment assignment becomes known.
- The study is stopped by (*include as appropriate)* Health Canada, the National Cancer Institute (NCI), the Research Ethics Board (REB), the Food and Drug Administration (FDA), or the study sponsor. The study sponsor is the organization who oversees the study.

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 their 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, trained staff will be available throughout the conduct of the study who can respond immediately. Necessary medical treatment will be made available at no additional cost to you. As soon as possible, notify the research team. 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 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, explanation must be provided, with a statement that treatment options will be discussed with the study doctor.

Researchers need to inform participants how and when study results are likely to be available and how to access them. If results will not be available, this needs to be stated. With industry-sponsored research involving study centers worldwide, the results may not be available for several years after the participant has completed their participation, and it is possible that they may only be available on a clinical trial website like clinicaltrials.gov. TCPS 2 (2022) Article 4.8 states that "Informing participants of the research results is as important as disseminating results to the research community".

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 {indicate whether individual or aggregated} by *{time}* from *{Principal Investigator or web site, etc}.*
Also, provide information on how results will be disseminated (i.e. thesis, articles, reports, etc) and whether participants will have the opportunity to request a copy of the results once available.

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, meals, etc.) as a result of participation

and whether or not these will be reimbursed, and what is required to be reimbursed (i.e., receipts). If an honorarium is to be paid (instead of reimbursement for specific expenses), the total dollar amount should be specified. The honorarium should be described as a way to reimburse participants for their time, travel expenses, and the inconvenience of being a research participant. The amount should not be so large or attractive as to encourage reckless disregard of risks, nor should it contribute to undue inducement and thus negate the voluntariness of consent (TCPS 2 (2022) Article 3.1). Participants who withdraw early are not to be penalized for doing so and should be informed that they will receive compensation proportionate to their time in the study. If the dollar amount exceeds $100, the researchers need to disclose that Social Insurance Numbers will be collected from participants and retained by the institution/USask for tax purposes.

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. Expenses for study visits will be reimbursed if they are first discussed and approved by the Study Doctor {*or research team*} before the costs are incurred, and receipts are submitted.

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. Compensation 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. Any personal information collected as a record of compensation payment will be stored separately from the data for 7 years for auditing purposes. (If the dollar amount exceeds $100, participants need to be informed that Social Insurance Numbers will be collected and retained by the institution/USask for tax purposes).

WILL MY PARTICIPATION BE KEPT CONFIDENTIAL?

This section is required for all studies. It is used to remind a research participant of their 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 **confidentialit**y (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). For all statements regarding confidentiality of research records, it is important to keep in mind that where legal privilege exists between physicians and patients (or counselor and client), the same privileges do not apply to investigators and participants. Absolute confidentiality can never be guaranteed, nor should it be implied in research. In rare instances, it is not possible to ensure confidentiality, as some cases require mandatory reporting. For example, suspected child abuse, self-harm, and communicable diseases. When such cases are possible and relevant to the study, participants should be made aware of this limitation in the consent form.

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. No information that discloses your identity will be released or published without your specific consent to the disclosure, or as required by law. The study data will be stored securely {*in a locked cabinet contained within a locked office under the supervision of the PI and/or by approved electronic storage methods {xyz}, by the study team for a minimum of choose one of the following: 5 years after the end of the research project's records collection and recording period OR 5 years from the submission of the final project report OR 5 years from the date of publication of a report of the project research OR 5 years from the date a degree related to this research project is awarded to a student* }. Research records and medical records identifying you may be inspected by the University of Saskatchewan Biomedical Research Ethics Board, or regulatory authorities for quality assurance and monitoring purposes.

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 disclosed.

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 institution}***. 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 to the disclosure, or as required by law. Rarely, your study documents may be obtained by courts of law. 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 their 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. 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, they 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 should a participant have questions about the study, and to provide contact information for 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 their 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 Biomedical Research Ethics Board, at 306-966-2975 (out of town calls 1-888-966-2975) or in writing at ethics.office@usask.ca. The Biomedical 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 Biomedical Research Ethics Board.

Required wording (for clinical trials):

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, a database of privately and publicly funded clinical studies conducted around the world. Registration is required by several governing agencies. This website will not include information that can identify you. At most, the website will include a summary of the study results. You can search this website at any time.

CONSENT TO PARTICIPATE

This section is required for all studies. The participant is signing the form to indicate that they have read (or otherwise been informed) and understand the information concerning the conduct of 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 individuals who are unable to provide consent (e.g., minors or individuals who do not have capacity), TCPS 2 (2022) places certain conditions on when these individuals can be invited to participate in research (see Articles 3.9, 3.10, and 3.11). If these conditions are met, it should be determined whether a parent, guardian, or other authorized representative has the legal authority to give consent on the individual's behalf, and if so, that individual's consent must be obtained to participate in the research. Participants should be given the opportunity to provide their assent to participate. This is something that can be added to the main consent form, whereby the researcher would record whether assent was sought, and either obtained or refused on the signature page. Individuals, who verbally, or otherwise indicate refusal to participate (i.e., with body language) should not be enrolled in the study even if a representative is willing to provided consent on their behalf. If a participant becomes able to consent on their own (i.e., gains capacity) during the course of the study, consent from the participant must be obtained in order for participation to continue.

The basis in Saskatchewan law for a "legally authorized representative" to make decisions for an individual without capacity for research purposes is unclear. 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, such as the participant's parent or guardian or as someone who was entrusted by the participant, while the participant had capacity, to make such decisions for them when they themselves are unable. The authorized representative is entrusted to make 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 accurately describes the information presented in the native language.

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 and/or the individual consenting on their behalf, if applicable.

Suggested wording

[Institutional logo/letterhead]

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 understand that this study may not provide any benefits to me.
- 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 understand that I am free to withdraw from this study at any time for any reason and I understand that 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 as soon as possible if I feel I have had any unexpected or unusual symptoms.
- I give permission for the collection, use and disclosure of my personal health information for the research purposes, as described in this consent 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

- *(If applicable)* 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 {*insert name of governing body/institution}* permission to disclose my health care information to the study investigators Yes / No

My signature below indicates that I agree to participate in this study:

Signature Date

Printed name of participant:

Printed name of person obtaining consent: (e.g. Study Coordinator) Signature Date

CONSENT SIGNATURE OPTIONS- for Minors or Individuals Without Capacity:

I consent to participate in this study.
(Person conducting consent discussion to choose appropriate option below, and mark others as "N/A".)

Option 1 - Participant Consent:
Minors deemed to have the capacity to understand the significance of the research and the implications of risk and benefits to themselves, have had the study and study procedures explained to them. Signed consent using this form was obtained from the minor. The parent/legal guardian/authorized representative signature was not obtained because the minor was deemed to have capacity to consent on their own behalf as assessed by the study investigator(s).

Printed Name of Participant Signature of Consenting Participant

Date (dd/mm/yyyy)

Option 2 – Written Participant Assent for Those Not Deemed Able to Consent:
Signed consent was obtained from the parent/legal guardian/authorized representative and written assent was obtained from the participant.

Signature of Assenting Participant Date (dd/mm/yyyy)

Consent Signature of Parent/ Legal Guardian/ Authorized Representative Date (dd/mm/yyyy)

Printed Name of Parent/ Legal Guardian/ Authorized Representative Relationship to Participant

Option 3 - Verbal Participant Assent for Those Not Deemed Able to Consent:
Signed consent was obtained from the parent/legal guardian/authorized representative and verbal assent was obtained from the participant.

Verbal Assent from Participant □ Yes

Consent Signature of Parent/ Legal Guardian/Authorized Representative Date (dd/mm/yyyy)

Printed Name of Parent/ Legal Guardian/Authorized Representative Relationship to Participant

Option 4 – Parent/Legal Guardian/Authorized Representative Consent for Those Not Deemed Able to Consent (Minor or Individual Without Capacity):
Signed consent was obtained from the parent/legal guardian/authorized representative on behalf of the participant.

Consent Signature of Parent/ Legal Guardian/Authorized Representative

Date (dd/mm/yyyy)

Printed Name of Parent/ Legal Guardian/Authorized Representative

Relationship to Participant

IMPARTIAL WITNESS - *This section is required if the participant (or parent/legal guardian/authorized representative) is unable to read or unable to write.*
I attest that I am not involved in the research study, and I was present during the consent discussion. The consent form was accurately explained to, and apparently understood by, the participant (or parent/legal guardian/authorized representative), and consent was freely given by the participant (or parent/legal guardian/authorized representative).

Consent Signature of Witness

Date (dd/mm/yyyy)

Printed Name of Witness

STATEMENT OF PERSON EXPLAINING CONSENT
I have explained to the participant and their parent/legal guardian/authorized representative the nature and purpose of the above study. The participant and their parent/legal guardian/authorized representative signing this form have been given enough time to review the information. There has been an opportunity to ask questions and receive answers regarding the nature, risks, and benefits of participation in this research study. The participant and their parent/legal guardian/authorized representative appear to understand the nature and purpose of the study and the demands required of participation.

Signature of Person conducting consent discussion

Date (dd/mmm/yyyy)

Printed Name of Person conducting consent discussion