Instructions for Informed Consent Form Development

The informed consent form (ICF) is one component of the informed consent process. Further guidance may be found in the HREB Guidelines for Consent for Research found under the Attachments tab in the Researcher Portal.

Brief instructions to consent authors are highlighted in this colour and/or [enclosed in square brackets]. This text should be removed prior to REB submission, i.e. not included in the consent form for participants.

Edit the text examples as necessary to make the language specific to the study question since many statements throughout the template are generic.

Examples are not given for every study situation. Consent authors should review all examples in a section, even if the example is for a different study type, to identify language that may apply to their study.

Participant Study Calendars: Consider providing an easy-to-read-and- understandable participant study calendar. A participant study calendar may be included as an appendix or included in the main consent document.

Eliminate repetitive information.

Define all acronyms when they first appear and limit their use.

For clinical trials: Use the term ‘study doctor’ when referring to physicians involved in a clinical trial, to ensure there is no confusion with the treating or primary care doctors.

Please delete this instruction page from the consent form prior to REB submission.

Participant Initials: _____

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Insert Letterhead/Logo

Consent to Take Part in a Clinical Trial

TITLE: Please provide a simplified/lay protocol title

PROTOCOL TITLE/NUMBER: Please provide the full protocol title and protocol number

STUDY DOCTORS: **Phone number:**

SPONSOR:

General information

Introduction

You have been invited to take part in a research study. Taking part in this study is voluntary. You may choose to take part or you may choose not to take part in this study. You also may change your mind at any time. If you decide to stop participating in the study, your study doctor will discuss other options with you. Whatever you choose it will not affect your usual health care and you will not lose any benefits to which you are entitled.

This consent form has important information to help you make your choice. It may use words that you do not understand. Please ask the study staff to explain anything that you do not understand. It is important that you have as much information as you need and that all your questions are answered. Please take as much time as you need to think about your decision to participate or not, and ask questions about anything that is not clear. You may find it helpful to discuss it with your friends and family.

You cannot take part in this research study if:

- You are taking part in another drug/device study at this time
- You have finished another drug/device study in the last 30 days [unless otherwise stated in protocol].

If you have been in another research study in the last year you should tell the study doctor.

1. Why am I being asked to join this study?

Give a brief statement of why this particular person was considered as a possible candidate for the trial followed by a statement about the main objective/purpose of the study.

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See examples below and edit as applicable.

We are inviting you to take part in a research study because you have (condition/disease).

- **Pilot Studies:** This research is called a "pilot study" or "feasibility study" and is done to test the study plan and to find out whether a bigger study is possible. This type of study involves a small number of participants and so it is not expected to prove safety or effectiveness. Knowledge gained from pilot or feasibility studies may be used to develop future studies that may benefit others. Participation in a pilot study does not mean that you will be able to participate in a future larger study.

- **Phase 1(dose finding/escalation):** This research is being done to find the highest tolerated dose [or most effective dose] of a new drug called [insert drug name] that can be given without causing unwanted side effects. All participants are given [insert drug name] and are watched very closely to see what side effects they may have [such as x, y and z] and to make sure the side effects are not severe. Participants who are enrolled in the study early will get lower doses, and those later on will get higher doses of [insert drug name]. This increase of dosage is called dose finding.

- **Phase II studies**: This research is being done to see what effects (good and bad) [insert drug name/device/intervention] has on [insert study population (e.g., children with disease/condition)].

- **Phase III studies:** This research is being done to see what effects (good and bad) [insert drug name/device/intervention] has on [state disease condition for which drug is being tested] compared to the best available or current standard treatment given for [disease/condition] at this time. We want to see which treatment/therapy is better.

- **Phase III placebo controlled studies:** This research is being done to find out whether it is better to receive [insert name(s) of drug/product/agent/device], or better to receive no additional intervention. To do this, some of the participants in this study will get [insert name(s) of product/agent/device] and others will receive a placebo (a substance that looks like the study drug/natural health product/drug/device but does not have any active ingredients). The placebo in this study is not intended to have any effect on your specify condition. A placebo is used to make the results of the study more reliable.

- **Phase IV studies:** This research is being done to learn more about the long-term effects (good and bad) of [insert drug name/device/intervention] on [insert disease/condition] to obtain additional information about [specify purpose e.g., benefits, side effects, etc. or to compare it with another approved intervention].

- **Extension Study:** You are near completion of the main study in which you received [insert intervention] over [list time period - e.g. ## weeks]. In this extension study, all participants will receive the study drug. If you were on placebo, you will now receive the active study drug. If you were on the active study drug, you will continue on your previous dose. Please note that any mention of **possible future** extension studies should not be included in this consent form.

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2. What is being tested?

Briefly describe the drug, device or procedure indicating whether it is experimental and/or approved by FDA and/or Health Canada (if applicable) and give the number of people who, to date, have been exposed to the item being evaluated. You may provide a statement about what was studied in the previous research (e.g. dosage, risk/safety profile, efficacy).

3. How many people will take part in this study?

Briefly describe where the study is being done, (e.g. Newfoundland, Canada, North America, world-wide) and how many people are expected to take part in total and at the local site.

For example: This study will take place in several countries around the world. The study will enroll a total of 5000 people. We expect to enroll about 10 patients at this clinic/hospital.

4. How long will I be in the study?

Briefly summarize in one or two sentences, how many visits will be required, how long the visits will last, and the duration of the study.
For example, You will be expected to come to the clinic for 20 visits over the next 24 months. Each visit will last 1-2 hours.

5. What are the study groups?

Provide a brief description of the study groups. For studies with multiple groups, indicate how many participants will be in each group, if known. Include how the treatment will be administered, if applicable.
For randomized studies, include the probability of being assigned to each arm. Briefly describe the blinding and un-blinding procedures as applicable

For example:
This study has 2 study groups. You will not be told which group you are in. We will use a computer to assign you to one of the study groups. 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. You will have [insert appropriate probability] chance of being in Group 1 or Group 2. Neither you nor your doctor will know which group you are assigned to but your doctor will be given this information if it is required.

Group 1
If you are in this group, you will get the usual drug [name of usual drug] used to treat [disease/condition], plus the study drug [insert name of study drug]. You will get these drugs [as pills taken by mouth/through a vein in your arm] twice a day. There will be about [insert number] people in this group.

Group 2
If you are in this group, you will get the usual drug, [insert name of usual drug], used to treat [disease/condition], plus a placebo. A placebo looks like the study drug, but contains no medication. You will get the drug and placebo [as pills taken by mouth/through a vein in your arm] twice a day. There will be about [insert number] people in this group.

6. What will happen if I take part in this study?

Summarize what will happen to a person who takes part in the study. It isn't necessary to list every test/procedure. These should be placed in a calendar/table immediately following the signature page. Only include information regarding the interventions that are not included in the standard of care for this participant.

Examples include (please edit as applicable):
If you agree to take part in this study, the following tests and procedures will be done in addition to your usual care. These tests and procedures are being done for research purposes. If you were not in the study, these tests or procedures may not have been done, and the information from them may not have been collected.

- Ask you questions about your health and any medications you are taking at each study visit
- Blood samples will be taken by inserting a needle into a vein in your arm. Specify amount of blood to be collected and timing. **For example**: About 1 tablespoon (5 ml) will be taken at every study visit, or x times a year. These blood samples will be sent to a laboratory in [city, country] where they will be examined to [explain the purpose e.g. confirm your diagnosis or test your kidney and liver function]. To protect your identity, the information that will be on your samples will be limited to [specify which identifiers will be on the samples e.g. study code, initials, pathology identification number].
- Urine will be collected [specify number of samples to be collected and timing e.g. 3 times per year]. These urine samples will be sent to a laboratory in [city, country] where they will be examined to [explain the purpose e.g. test for pregnancy if you are of child bearing potential].
- Tissue Collection - A small sample of your tumor that has already been removed by a previous surgery or biopsy will be obtained by the study doctors doing this study. No further surgeries or biopsies are required of you for this purpose. If a fresh tissue sample is required: If a previous tissue sample is not available, you will need to have a tissue biopsy. A tissue biopsy is a type of surgical procedure, which will remove [state how much tissue is to be taken e.g. a pea size piece of tumor]. Explain in lay language whether this will be done using a local or general anesthetic and whether overnight hospital stay may be required. These tissue samples will be sent to a laboratory in [city, country] where they will be examined to [explain the purpose e.g. to confirm your diagnosis].
- XRays/Scans/MRI twice a year
- Physical exam each visit/or x times a year
- Questionnaires about [e.g. your health] [frequency e.g. twice per year]. The purpose of the questionnaire is to [e.g. understand how your treatment and illness affects your quality of life]. Each questionnaire will take about x minutes to complete. Some of the questions are personal; you may choose not to answer these if you wish. [If the questions are of a sensitive nature,

include potential for emotional distress in the Risks section and what type of help will be provided if this happens.]

- Participant Diaries - You will be asked to keep a diary of when you take your study medication. Please record the exact time of taking each dose in your daily diary. You will be asked to return the diary to the clinic/hospital.
- If central review is a mandatory component of the research, include a description of the material(s) being reviewed centrally, including the type, reason, location, retention and identifiers. E.g. Copies of your CT scans/Surgical specimens will be collected as part of this study. The copies will be sent to [specify institution and location conducting review], where they will be [reviewed, stored], and kept until [specify retention period] when then they will be destroyed. This process is required for [include description of rationale, e.g., quality assurance and data management]. To protect your identity, the information that will be on your [specify material, e.g. scans/specimens] will be limited to [specify which identifiers will be on the review material(s)].
- Include whether standard treatment will be withdrawn or if there will be a wash out period.
- A detailed list of all tests and procedures may be found on a table after the Signature Page.

7. Are there risks to taking part in this study?

When the information is available, please categorize the frequency of risks using bulleted list in lay language.

All potential risks, discomforts and inconveniences of being in the study – physical, emotional, social – should be explained. Severe, irreversible and fatal outcomes should be stated precisely.

When relevant, explain the ramifications of potential harms, e.g. abnormal liver function, and whether they are reversible.

Specific symptoms for serious side effects of which the participant should be aware should be included and instructions provided about seeking medical assistance, if applicable.

It is not necessary to include the risks associate with the standard of care/care that the participant will receive if not participating in this study unless there are risks associated with the combination of treatment.

For example:

Participating in this study will put you at risk for the side effects listed below. You should discuss these with your study doctor. As with any treatment additional unexpected and sometimes serious side effects are a possibility. The risks and side-effects of the standard procedures will be explained to you as part of your usual care and therefore are not listed here.

The tables below show a list of side effects seen in the people who have taken this drug/treatment/used this device/had this procedure. It is important to remember that there may be side effects or risks that are not known at this time. If you experience any side effects, please discuss them with your study doctor.

COMMON : In 100 people receiving xxxx, 20 or more may have:
OCCASIONAL: In 100 people receiving xxxx, 5 to 20 may have:
RARE: In 100 people receiving xxxx, 1-4 may have:

If there are potential risks associated with the disclosure of a diagnosis or screening test result in the case of genetic conditions, please describe the procedure for addressing the situation.

Please add language for mandatory reporting of test results, if applicable.

When limited numbers of individuals have been exposed to the drug (less than 100), and the risks cannot accurately be quantified, the following language should be included (if applicable):

For example:
As of [date], only x people have been given this drug and the side effects that have been reported are:

- <X> experienced xxx
- <X> experienced xxx

It is not yet known if these side effects are caused by [agent] or how likely these side effects will be.

Or, if applicable: The study drug is in an early phase of development and so the side-effects in humans are unknown at this time. Animal studies to date show xxx.

If the study drug will be used in combination with standard treatment, the consent should include the following:
For example:
You will [receive/continue to receive] the standard treatment for the condition you have. An experimental intervention is being added. This combination could change the side effects or the effectiveness of the standard treatment. This could mean that you experience more side effects than you would with the standard treatment alone. It could also mean that the standard treatment does not work as expected.

Please include any potential discomforts or inconveniences in this section. Examples include: discomfort answering questionnaires; blood draws may cause pain, bleeding, bruising and/or development of a small scars; attending multiple study visits.

8. What about pregnancy and breast feeding?

The following are approved statements on pregnancy and breast feeding for participants. **Select the statements relevant to this study or edit as required.**

- There may be unknown risks or side effects to a fetus or nursing child.

- You should not become pregnant or breast-feed while taking part in this study.

- If you choose to take part and if you are able to become pregnant:
  1. You will be required to provide a blood and/or a urine sample(s) for a pregnancy test (s).
  2. You will be required to use a reliable form of birth control throughout the study and for (xx weeks) after the last dose of the study drug. The doctor will discuss this with you.

- If you become pregnant while taking part in this study or within 30 days of stopping the study drug:
  1. You must notify the study doctor immediately.
  2. If you are taking study drug, it will be stopped immediately.
  3. The doctor will tell the sponsor. They may want to know the outcome of your pregnancy. This is OPTIONAL and there will be a separate consent form for this option.

- If you are a male whose partner could become pregnant, you will be required to use a reliable form of birth control throughout the study and for (xx weeks) after the last dose of study drug. The doctor will discuss this with you.

- There are no special requirements for contraception for men or the female partners of men taking part in this study.

- If your partner becomes pregnant while you are taking part in this study or within 30 days of stopping the study drug you must notify the study doctor immediately. The study doctor will tell the sponsor. They may want to know the outcome of the pregnancy. This is OPTIONAL and there will be a separate consent form for this option.

9. What are the possible benefits of participating in this study?

There may not be direct benefit to you from taking part in this study.

If applicable, include: We hope that the information learned from this study can be used in the future to benefit other people with [disease/condition].

10. Are there other choices?

In your clinical setting, what is the standard effective therapy you would use to treat eligible patients who decide to not participate in this study?'

For example:
If you choose not to participate in this study or to withdraw at a later date, the following treatment options may be available to you:

- List those that you will use **in your clinical setting**

- Taking part in another study if there is one available.
- Getting comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by [condition]. It does not treat [condition] directly, instead it tries to improve how you feel.

You can discuss these options with your usual doctor or your study doctor before deciding whether or not to participate in this research project.

Suggestion for studies using healthy volunteers:
You do not have to take part in this study.

11. What happens at the end of the study?

Choose from of the following statements what participants can expect at the end of this study or edit to apply to this study:

- [Drug/device] will be available through the study but only until your participation ends.
- [Drug/device] will be available through the study but only until the end of the study.
- [Drug/device] will be available and participant will be expected to pay for the drug/device as they usually do.
- At the end of this study, the experimental treatment will continue to be provided free of charge.

12. What are my responsibilities?

Please edit the list below as required for this study:

If you take part in this study you will be expected to:

- Come to all study appointments
- Follow the directions of the study doctor
- Report all medications that you are taking or plan to take (prescription and non-prescription and supplements, including vitamins and herbals), and check with the study doctor before starting, stopping or changing any of these. This is for your safety as these may interact with the intervention you receive on this study
- Report any changes in your health, including side effects
- Report any problems you think might be related to taking part in the study
- Report any doctors' visits or hospital stays outside of this study
- Return any unused study medication, diaries and questionnaires
- Tell the study doctor about your current medical conditions
- Tell the study doctor if you are thinking about participating in another research study
- Tell the study doctor if you become pregnant or father a child while participating on this study
- Avoid drinking/eating specify what and for how long
- Stop taking name for specify washout period
- Tell the study staff if you change your mind about being in this study.

[Insert name of study intervention] is for you alone, and must not be shared with others. If applicable, include: If someone accidentally takes insert name of study intervention, include instructions e.g., they should immediately go to the nearest emergency department.

13. If I decide to take part in this study, can I stop later?

Note: requiring a written notification is not acceptable. It is the study team's responsibility to document the request. Verbal notification is sufficient. Parents/patients should not be asked to go through the additional burden of writing a letter for documentation purposes.

It is your choice to take part in this study, participation is voluntary. You can change your mind at any time during the research study. The study team may ask why you are withdrawing for reporting purposes, but you do not need to give a reason to withdraw from the study if you do not want to. Withdrawal from the study will not have any effect on the care you (or your family, if applicable) will receive. If you decide to leave the study, you can contact your study doctor or a member of the study team to let them know. Your study doctor will discuss other options with you.

Please describe the process for withdrawal and any limitations to the withdrawal. **You may select an option from the sample language below or edit to suit the study:**

- You may choose to withdraw from the study treatment but continue to have follow up study visits. Your study doctor or designate will discuss what study procedures will be carried out if you choose this option. The study staff will continue to access your medical records and use your medical data and study information as described in this consent form for the purposes of this study.
- You may choose to withdraw from study treatment and study procedures but allow the study team to contact you regularly according to the study visit schedule and to access your medical records and use your medical data and study information as described in this consent form for the purposes of this study.
- You may fully withdraw from this study. This means that the study doctor and study staff will no longer access your medical records or use your data for research and all data collected about you will be destroyed. Any remaining biologic samples will also be destroyed. We will no longer contact you for any reason. Any data that has already been merged with other data and analyzed cannot be destroyed or removed from the study. This is because we have to preserve the study's scientific integrity. However, your data will not be used in future research. If you decide to withdraw, you may still be asked to come for a final safety study visit to ensure your safety.
- You may withdraw from this study. The study team will have a discussion with you about what will happen to the information about you [and/or your samples] already collected. Your study doctor will notify the sponsor who will ensure that the information/samples are [returned to the hospital from which they were obtained if needed, or destroyed]. You can request withdrawal of your specimens until [insert expected time point], at which point the code that links you to your sample will be removed. It won't be possible to return samples after this because the researchers will not know which sample is yours.
- You have the right to request the destruction of your information [and/or samples] collected during the study, or you may choose to leave the study and allow the investigators to keep the

information already collected about you until that point.
- State whether or not the participant may continue to participate in this main part of the study, if they withdraw these samples.

If your participation in this study includes enrolling in any optional studies or long term follow-up, you will be asked whether you wish to withdraw from these as well.

14. Are there other reasons why I might stop being in the study?

Edit as required.
The study doctor may take you off the study if:
- Your health changes and the study is no longer in your best interest.
- Your study doctor no longer feels this is the best treatment for you.
- Your study doctor feels that side effects are harming your health
- New information becomes available and the study is no longer in your best interest.
- You are unable to complete all required study procedures
- You need treatment not allowed in the study
- If you plan to or become pregnant
- The study is stopped by (sponsor), the Health Research Ethics Board (HREB), Food and Drug Administration (FDA) (delete if not applicable), Health Canada (delete if not applicable), or your study doctor.
- Your treatment assignment becomes known to you or your study doctor

If you are asked to leave the study, the reasons for this will be explained to you and you will have the opportunity to ask questions about this decision. If your participation in the study is stopped, your study doctor will provide information about how to stop safely. If this happens, it may mean that you would not receive the study intervention for the full period described in this consent form. Your study doctor will arrange for you to continue your care outside of the study.

15. What about new information?

It is possible that during the study we will get new information about a more effective treatment or other information that may affect your willingness to remain in the study. If this happens, you will be notified about the new information in a timely manner. You will be asked whether you want to continue taking part in this study and you may be invited to sign a new consent form, if you decide to continue in the research study.

A description of this clinical trial will be available on [insert website] as required by local and international laws and regulations. This website will not include information that can identify you. You can search this website at any time.

16. Will it cost me anything?

Describe any reimbursement and/or compensation provided to participants, or state if no compensation is provided. Include how they should claim for reimbursement (i.e. if receipts are required). If there are multiple visits, describe when they will be compensated (e.g., two gift cards of value X, one at each visit; one gift card at the last visit).

Compensation

If no payment/reimbursement:
You will not be paid or reimbursed for any expenses related to being in this study.

If reimbursed:
We will reimburse you for all your reasonable out of pocket expenses, such as meals, parking and transportation costs to and from the clinic, up to a maximum of $$. If you stop taking part in the study, we will pay you for expenses incurred up until that point.

If compensated:
As a token of our appreciation, you will be given $$ [if providing gift card, provide category of stores or specific store name] for your participation in this study. Such payments must not be weighted toward the end of the study, as an incentive to complete participation.

For studies providing remuneration of $500 or more in one year, please check with your institution's finance department to clarify whether they will need the participant's Social Insurance Number to issue a T4. If so, disclose in the consent form.

Research related injury

If you become ill or injured as a direct result of taking part in this study, medical care will be available at no additional cost to you.

Other costs

The costs of your medical treatment will be paid for by your provincial medical plan to the extent that coverage is available. All research-related medical care and treatment and any related tests that you will receive during your participation in this study will be provided at no cost to you.

There may be extra costs that are not covered by your medical plan that you will have to pay yourself such as physiotherapy, pain medications or medications to prevent or alleviate side effects.

The study drug/agent will be given to you free of charge as long as you are in the study.

Participant Initials: _____

Consent Version Date: _____

17. What about my privacy and confidentiality?

Protecting your privacy is an important part of this study. During your participation, the study study staff will collect and use information from your medical records such as:

Edit as necessary.

- gender
- date of birth
- new or existing medical tests or procedures
- medications
- medical conditions (sensitive information about HIV,genetic testing, substance use and/or mental health problems)

The personal health information or personal information collected about you will have your directly identifiable information removed (i.e., name, MCP) and replaced with a code or with a "study number". There will be a master list linking the code numbers to names. The study doctor is responsible for keeping it separate from the samples and personal health information. This link will not be available to the [Sponsor/Funding agency/Coordinating centre].

Study information collected during the study will kept at this site and stored in a secure, locked place that only the study staff will be able to access. After the study closes, study information will kept as long as required by law, which could be 15 years or more. This information will be stored [name the appropriate location]. [Name the appropriate person/role] is the person responsible for keeping it secure.

Study information sent to the sponsor, and companies working for the sponsor, will be stored in a secure central database. When the results of this study are published or presented at scientific meetings, your name and other personal information will not be used in the publication.

All information that identifies you will be kept confidential, and to the extent permitted by applicable laws, will not be disclosed or made publicly available, except as described in this consent document. Every effort to protect your privacy will be made. Even though the risk of identifying you from the study data is very small, it can never be completely eliminated. If there is a breach of your privacy resulting from your participation in this study you will be notified.

If data or samples will be sent outside of Canada:
Your study information and/or samples, will be sent outside of Canada so there is a possible increase in the risk of identifying you from the study data because the laws in other countries dealing with protection of information may not be as strict as in Canada. However, all study data and/or samples that are transferred outside of Canada will have your directly identifying personal information removed (such as your name, address, medical health number or contact information). Any information will be transferred in compliance with all relevant Canadian privacy laws. By signing this consent form, you are agreeing to the disclosure of your coded information to organizations located outside of Canada.

If their participation will be noted in their clinic chart:

Participant Initials: _____

Consent Version Date: _____

Your participation in this study will be noted in your hospital or clinic chart. This is recommended to ensure your safety so that any treating physician will know that you are participating in a research study.

For studies using smartphones, apps or applicable technology, please provide details on the security/privacy/limits to the confidentiality.

If email will be used for study purposes (e.g., distribution of questionnaires, etc.), please add:
Communication via e-mail is not absolutely secure. We do not recommend that you communicate sensitive personal information via e-mail.

18. Who will see my medical information?

Note: If there will be disclosure of personal identifiers, i.e., disclosed on any research-related information/documents including samples or scans, or as part of the unique identifier, these disclosures must be justified in the REB application and approved. Please ensure that you are aware of institutional and REB policies with respect to the disclosure of personal identifiers.

Representatives from the following organizations may come to the hospital/clinic to look at your personal health information under the supervision of the study staff to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines:
Edit as needed

- Sponsor Name, the company that makes the (drug/device/intervention) and its representatives and partner companies;
- Representatives of the Health Research Ethics Board
- Representatives of Health Canada, group of people who oversee the use of drugs in research in Canada, and (if applicable) other regulatory bodies such as the United States Food and Drug Administration (FDA).

We may continue to review your health records that you have consented for the study to access for a period of time after your last study visit in order to check that the information we collected is correct.

If identifiable data will be sent outside the institution:
This study requires the transfer of identifiable information to [insert name of institution/individual] for the purposes of [specify purpose]. The following information will be transferred:

- Specify identifiable information to be transferred
- Indicate how this identifiable information will be protected, used, and disclosed.

Your access to records

- You have the right to see the information that has been collected about you for this study. If you wish to do so, please contact your study doctor.
- If applicable, include the following information: This is a ‘blinded’ study, which means that the research team cannot tell you which drug you are taking until the study ends. This is to prevent

either you or your doctor from knowing which study treatment you received until the results are reported.

19. What are my rights when participating in a research study?

You have the right to receive all information that could help you make a decision about participating in this study, in a timely manner. You also have the right to ask questions about this study at any time and to have them answered to your satisfaction.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

Signing this form gives us your consent to be in this study. It tells us that you understand the information about the research study. When you sign this form you do not give up any of your legal rights against the study doctor, sponsor or involved institutions for compensation, nor does this form relieve the study doctor, sponsor or their agents of their legal and professional responsibilities.

You have the right to be informed of the results of this study once the entire study is complete. Describe how the study results will be provided (Refer to Dissemination sections of the application).

You will be given a copy of this signed and dated consent form prior to participating in this study.

20. Commercialization:

Edit as applicable
It is possible that a commercial product may be developed as a result of this study. You will have no right to any products that may be created as a result of this study or any future research studies using this research study data. You will not receive royalties from any products that may be created as a result of this study or any future research studies.

21. Declaration of financial interest, if applicable

Describe any conflict of interest that exists or may appear to exist as it relates to any of the investigators, study staff or member of their immediate family. NOTE: A conflict of interest exists if there is a potential benefit to the investigator(s), study staff or member of their immediate family beyond the professional benefit from academic achievement or presentation of the results. Examples include, but are not limited to, speaker's fees, travel assistance, consultant fees, honoraria, gifts, and intellectual property rights such as patents. A declaration of conflict of interest should include the identity of the person with the conflict of interest, the type of incentive or inducement, and its source.

A conflict of interest can occur when a person or group has more than one interest. In research, the people who run or work on studies must tell you if they have a conflict of interest.

Participant Initials: _____

Consent Version Date: _____

If there are no conflicts, state:
There are no conflicts of interest to declare related to this study.

If a conflict exists, see below example language
Dr. X, declares that he/she [may/will] gain financially by being involved in this study because he/she will be paid by [insert name of sponsor/agency] for his/her time and effort during the study. This may create a competing interest or conflict of interest.
OR
As a result of his/her participation in this study, Dr. X [has received/may receive] one or more of the following benefits from [insert name of sponsor/agency]: [speaker's fees, travel assistance, industry-initiated research grants, investigator-initiated research grants, consultant fees, honoraria, gifts, intellectual property rights such as patents, etc.]. This may create a competing interest or conflict of interest.
OR
The spouse of Dr. X owns shares in the company [insert name of company/sponsor] that is sponsoring the study and may benefit financially if the outcome of the study shows that the product helps patients. This may create a competing interest or conflict of interest.

22. What about questions or problems?

If you suffer a research-related injury or if you have any questions about taking part in this study, you can talk to your study doctor. You can also meet with the study doctor who is in charge of the study. That person is:

Insert Study Doctor's Name and Phone Number

You can also talk to someone who is not involved with the study at all. They can tell you about your rights as a participant in a research study. This person can be reached through:

Ethics Office at 709-864-8871
Email: info@hrea.ca
Web: www.hrea.ca

Participant Initials: _____

Consent Version Date: _____

Signature Page

My signature on this consent form means:

- I have had enough time to think about the information provided and ask for advice if needed.
- All of my questions have been answered and I understand the information within this consent form.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, without having to give a reason, and that this will not change the quality of care that I receive.
- I understand that it is my choice to be in the study and there is no guarantee that this study will provide any benefits to me.
- I am aware of the risks of participating in this study.
- I do not give up any of my legal rights by signing this consent form.
- I understand that all of the information collected will be kept confidential and that the results will only be used for the purposes described in this consent form.
- I allow access to health records and transfer of specimens and related personal health information as explained in this consent form.
- I understand that my family doctor [will/may] be informed of my study participation [include as applicable].
- I agree, or agree to allow the person I am responsible for, to take part in this study [include as applicable].
- [Insert any other research specific clauses that may be important to reiterate.]

Signature of participant	Printed name	Day Month Year
Signature of person authorized as substitute decision maker **[If applicable]**	Printed name	Day Month Year
Signature of person conducting the consent discussion	Name printed	Day Month Year

To be signed by the investigator:

I have explained this study to the best of my ability. I invited questions and gave answers. I believe that the participant/substitute decision maker fully understands what is involved in being in the study, any potential risks of the study and that he or she has freely chosen to be in the study.

Signature of investigator	Name Printed	Day Month Year

Participant Initials: _____

Consent Version Date: _____

Signature Page for Parent/Guardian

My signature on this consent form means:

- I have had enough time to think about the information provided and ask for advice if needed.
- All of my questions have been answered and I understand the information within this consent form.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse for my child/ward to participate or to withdraw from this study at any time, without having to give a reason, and that this will not change the quality of care that my child/ward receives.
- I understand that it is my choice for my child/ward to be in the study and there is no guarantee that this study will provide any benefits to me.
- I am aware of the risks of my child/ward participating in this study.
- I do not give up any of my my child/ward's legal rights by signing this consent form,
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
- I allow access to my child/ward's medical records and transfer of specimens and related personal health information as explained in this consent form.
- I understand that my child/ward's family doctor will/may be informed of my study participation
- [Insert any other research specific clauses that may be important to reiterate.]

I consent for my child/ward _____to take part in this study.

_____		_____
Signature of parent/guardian	Name printed	Day Month Year
_____		_____
Signature of person conducting the consent discussion	Name printed	Day Month Year
_____		_____
Signature of witness **[If applicable]**	Name printed	Day Month Year

To be signed by the investigator:

I have explained this study to the best of my ability. I invited questions and gave answers. I believe that the parent/guardian fully understands what is involved in being in the study, any potential risks of the study and that he or she has freely chosen for the child/ward to be in the study.

_____	_____	_____
Signature of Investigator	Printed Name	Day Month Year

Participant Initials: _____

Consent Version Date: _____

To be signed by the minor participant [if appropriate]
Assent of minor participant:

I understand the purpose of this research
I understand that it is my decision to take part in this study. I can stop taking part if I chose.
I understand that taking part in this research may not help me.
I understand that there may be risks to participating in this study.

I agree that I will take part in this study

_____

Signature of minor participant Day Month Year

_____

Name printed Age

Participant Assistance

Complete the following declaration only if the participant is unable to read:

- The informed consent form was accurately explained to, and apparently understood by, the participant, and
- Informed consent was freely given by the participant

Signature of Impartial Witness	Printed Name	Day Month Year

Complete the following declaration only if the participant has limited proficiency in the language in which the consent form is written and interpretation was provided as follows:

- The informed consent discussion was interpreted by an interpreter and
- A sight translation of this document was provided by the interpreter as directed by the research staff conducting the consent.

Interpreter Declaration and Signature:
By signing the consent form I attest that I provided a faithful interpretation for any discussion that took place in my presence, and provided a sight translation of this document as directed by the research staff conducting the consent.

Signature of Interpreter	Printed Name	Day Month Year

Participant Initials: _____

Consent Version Date: _____