When writing the consent, please remember to:

- Use plain (lay) language that is easy for a non-medical person to understand.
- Remove unnecessary repetition throughout the form; if technical words are used a simple definition in lay terms should be included beside the terminology in brackets.
- Please use "second person" voice - i.e., "You will be asked to ..."
- Use a size and font of text that is consistent and easy to read (size 11 or larger is recommended).
- Define all acronyms and abbreviations when they first appear.
- Use the term ‘study doctor’ when referring to physicians involved in the study to ensure there is no confusion with the treating or primary care doctors.
- Use ‘study treatment’ instead of ‘treatment’ so that it is clear that it is a study procedure and not standard of care.
- Use the term ‘participant’ instead of ‘subject’ at all instances to emphasize the voluntary nature of the participation.
- It should be clear to participants under whose auspices the research is being conducted and if the protocol requires a participant to leave one institution and complete some procedures in another institution that this is clear.
- Ensure that the final form is properly formatted and free of spelling or grammar errors.
- Keep the footer simple and short. It should only include the version date, pagination as “page x of y”, and initials (not required) on every page.
- After all edits have been made, all text should be black.
- The participant must be provided with a copy of the consent document and this should be stated. Example: This letter is for you to keep OR You will be given a copy of consent document once it has been signed.
- Consent documents originating in the USA must be adapted by the Canadian investigators to remove/alter clauses which are only appropriate to the American health care system.
- All consent documents should be printed on letterhead.

Do not state that “This study has been approved by the research ethics committee....” since this may appear to offer a guarantee of safety. This is to conform to Health Canada guidelines for study consent forms (http://www.hc-sc.gc.ca/sr-sr/advice-avis/reb-cer/consent/index-eng.php#cons).
1. **Document Title**
   Add particular study subgroups to the document title, if applicable. This enables everyone to differentiate between consent forms and groups within a study. (e.g., control group, optional sub-studies such as biomarker sample collection, genetic sample collection).
   Formatting: Centered, Bold and/or Underlined

   Letter of Information and Consent
   or
   Letter of Information and Consent – Control Group
   or
   Consent to Participate in a Research Study
   or
   Consent to Participate in an Optional Pharmacogenomic Sub Study

2. **Study Title**
   Enter the full title of study, exactly as it appears on the Protocol. Add protocol number if applicable.

3. **Principal Investigator**
   Enter the name with title and telephone number of the Principal Investigator.

   **Principal Investigator**
   Dr. John Doe, MD Cardiology, FRCP
   University Hospital (519) 123-4567 ext. 12345

4. **Co-Investigators** (optional)
   If you choose to enter the names and titles of Co-Investigators, the consent form will require a revision to be reviewed and approval by the REB, every time there is a change in the co-investigator.

   **Co-Investigators**
   Dr. Mary Jones, MD Cardiology
   Dr. James Wright, MD Immunology

5. **24 Hour Contact Information** (for Clinical Trials)
   Provide a 24 hour contact number for clinical trials. Please be sure to specify the type of number (i.e. Pager, locating number, etc.). If a locating number is used, please provide instructions to both the patient as well as any on-call physicians.

   **24 Hour Contact**
   Pager (519) 123-4567
   Locating Number (519) 123-4567: Please ask for the on-call Cardiologist and let them know that you are a study participant under Dr. Doe.
6. Sponsor Information

Enter the full name of all sponsor(s) as documented on the protocol, including funding source’s and intervention suppliers. Please also include in-kind contributions (even when there is no cash funding). The nature of the in-kind contributions informs the process for bringing in the in-kind.

7. Voluntary Participation

7.1. Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. You may leave the study at any time without affecting your [care/employment status/academic standing - choose only those that are applicable].

We will give you new information that is learned during the study that might affect your decision to stay in the study.

7.2. For survey studies or questionnaires, insert if applicable

You may refuse to answer any question you do not want to answer, or not answer an interview question by saying “pass”.

7.3. For studies involving Aboriginal populations, insert if applicable

If you are a First Nations or an indigenous person who has contact with spiritual 'Elders', you may want to talk to them before you make a decision about this research study. Elders may have concerns about some genetic procedures.

8. Conflict of Interest

Describe any conflict of interest that exists or may appear to exist. Conflicts of interest exist when an investigator(s), their Department/Division, or their institution, or their immediate family has financial or personal relationships that may compromise or present the appearance of compromising an individual’s, group’s or institution’s judgment in conducting, reviewing, or reporting research (beyond the professional benefit from academic achievement or presentation of the results). Examples include, but are not limited to, any funds or material support to a physician, Department or Division for research, education, infrastructure, study personnel, 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. See examples below.

The identify individual, e.g., study doctor, insert name, is receiving personal financial payment from Identify source of funds e.g., the study Sponsor for include reason for payment e.g., providing advice on the design of the study. You may request any details about this payment.

OR

There are no conflicts of interest to declare related to this study.
OR
This centre is receiving funds from [insert source of funds] to help offset the costs of conducting this research.
The doctor treating you also may be the doctor in charge of the study.

9. Introduction
Introduce the research, why the participant is being approached, and why this research is being done. If there are incompetent participants or if the participants are minors, the letter should address the participant, rather than the substitute decision maker (SDM) or parent/guardian who is signing the consent form on behalf of the participant.

If SDM involved, insert:
In this Consent document, “you” always refers to the study participant. If you are a substitute decision maker (SDM) (i.e. someone who makes the decision of participation on behalf of a participant), please remember that “you” refers to the study patient. If an SDM is needed for this study, you will be asked to review and sign this consent form on behalf of the participant.

Introduction
You are being invited to participate in this research study about [explain what the study is about] because you [explain WHY the individual is being approached and asked to participate].

10. Why is this study being done?
10.1. Provide background information on what prompted the need for this study
10.2. Explain the purpose of the study in lay terminology.
10.3. Describe the design of the study; Examples include the following:

Pilot study:
The purpose of this study, called a pilot study or a feasibility study, is to test the study plan and to find out whether enough participants will join a larger study and accept the study procedures. This type of study involves a small number of participants and so it is not expected to prove safety or effectiveness. The results may be used as a guide for larger studies, although there is no guarantee that they will be conducted. Participation in a pilot study does not mean that you will be eligible to participate in a future larger study.

Suggestion: Phase I Studies:
The purpose of this study is to test the safety of a describe, e.g., natural health product/drug/device, insert name(s) of product/agent/device, to see what effects it has on you and your specify condition. This is the first time this has been tested in people.

Or
The purpose of this study is to find the highest dose of a describe, e.g., natural health product/drug/device, insert name(s) of product/agent/device that can be tolerated without causing very severe side effects. This is done by starting at a dose lower than the one that does not cause side effects in animals. This is the first time this has been tested in people. Participants are given insert name(s) of product/agent/device and are watched very closely to see what side effects they have and to make sure the side effects are not severe. If the side effects are not severe, then new participants will be given a higher dose of insert name(s) of product/agent/device. Participants joining this study later on will get higher doses of insert name(s) of product/agent/device than participants who join earlier. Include next sentences if applicable This will continue until a dose is found that causes severe but temporary side effects. Doses higher than that will not be given.

Suggestion: Phase II Studies:

The purpose of this study is to find out what effects a describe, e.g., natural health product/drug/device, insert name(s) of product/agent/device, has on you and your specify condition.

Suggestion: Phase III Studies:

The purpose of this study is to compare the effects on you and your specify condition of a describe, e.g., natural health product/drug/device, insert name(s) of product/agent/device, compared to other natural health products/drugs/devices which are commonly-used for specify condition.

Suggestion: Phase III Placebo Controlled Studies:

The purpose of this study is to find out specify purpose, e.g., whether it is better to receive [insert name(s) of 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 natural health product/drug/device but does not have any active or medicinal 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.

Suggestion: Phase IV studies:

The purpose of this study is to look at an approved intervention to obtain additional information about specify purpose e.g., benefits, side effects, etc.

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

11.1. The number of people to participate.

Up to [#] people will participate in this study and we anticipate that up to [#] will be enrolled at this institution.

11.2. The length of the study.

It is expected that you will be in the study for [length of study]
This study should take **total length of study in months or years** to complete.

### 12. What will happen during this study?

<table>
<thead>
<tr>
<th>12.1. Assignment to a group</th>
</tr>
</thead>
</table>

If there is more than one study group, describe how participants are placed into study group(s). See suggestions below. If these suggestions are not applicable, provide a lay description appropriate to the specific protocol.

**Example for Randomized study:**
If you decide to participate then you will be "randomized" into one of the groups described below. Randomization means that you are put into a group by chance (like flipping a coin). There is no way to predict which group you will be assigned to. You will have *explain probability of randomization* e.g., equal; 50/50; 1 in 3 chance of being placed in either/any group. Neither you, the study staff, nor the study doctors can choose what group you will be in.

**Explanation whether participants or others will know which group the participant will be in.**
See suggestions below:

**For open label, randomized studies**
You will be told which group you are in.

**Or (single-blind studies)**
You will not know which group you are in, but the study doctor and study staff will.

**Or (double-blind studies)**
This is a double-blind study, which means that neither you, the study doctors, the study staff, nor your usual health care providers will know which group you are in. Your group assignment can be identified if medically necessary. Requests to reveal your assignment for your information or participation in other research studies will not be considered until this study has been completed and the results are known.

**Extension Study:**
You are near completion of the main study in which you received [insert drug/device/procedure/placebo] over [list time period - e.g. ## weeks]. In this extension study, all participants will receive the study drug for [list time period - e.g. ## weeks]. [List relevant additional information such as:] 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.
**Example for trials with intervention assigned based on protocol-specific criteria**

If you decide to participate then you will be assigned into one of the groups described below. The group you are assigned to will be determined by specify assignment criteria e.g. the treatment you have previously received. You will be told which group you are in.

If applicable, include the following:

Once a certain number of participants have entered the intervention phase of the study from all of the research sites combined, no more participants will be enrolled into the study at any site. It is possible that you may finish the screening phase and be ready to enter the intervention phase of the study, but not be enrolled into the study.

12.2. Inclusion/Exclusion Criteria (optional)

You do not have to list all the inclusion/exclusion criteria.

12.3. Do not define placebo as “dummy tablets” or “sugar pills”. Instead describe placebo as “a pill/procedure that looks real but contains no active ingredients.

**13. What are the study procedures?**

The Procedures section should outline what is expected of the participant. This section should be clear so that the participant is clearly informed of his/her responsibility. The following items are things to consider when writing this section of the Consent document:

13.1. Present procedures in bullet format

13.2. List the different types of study visits to take place (i.e. Screening, Baseline, Visit 1, End of Study Visit, Early Termination Visit, etc.). Include what is required of the participant at each of these visits.

13.3. Ensure that standard of care procedures are clearly differentiated from research related procedures. The LOI should focus on the research related procedures and discuss standard of care where necessary.

13.4. If bodily fluids/tissue is being collected: Quantify (ml, tsp, tubes, slides etc.) the amount of fluids/tissue to be taken at each visit.

For pharmacokinetics studies: indicate the frequency and the amount of blood (per draw and overall) to be taken and over what interval.

13.5. Number of study visits

There will be [#] study visits during your participation in this study.

13.6. If applicable, indicate if any hospitalizations are required and if procedures are to be performed outside of the institution. Should study procedures take place at different site, indicate so.

13.7. List and provide a description (if not obvious) of the different types of tests to be carried out on the participant. Examples are:

- Medical History
- Physical Exam
- Blood draw
- Catheter Blood draw
- Pregnancy Test: Specify if urine or blood or both will be taken and quantity
- X-ray
- MRI: Use of magnetic waves to take pictures of the inside of your body. You will have to lie still in a MR machine but will be able to speak to someone at all times.
- MRI with Gadolinium contrast: Use of magnetic waves to take pictures of the inside of your body. You will have to lie still in a MR machine but will be able to speak to someone at all times. Prior to the MR scan you will have a gadolinium contrast injection via IV (intravenous catheter) to evaluate blood vessels.
- ECG: An electrocardiogram is a test that measures the electrical activity of the heart. Patches attached by wires to a machine will be put on your chest so that the machine can record the pattern of your heart beats.
- Echocardiogram: A test that uses sound waves to create a moving picture of the heart to measure how well your heart is functioning. The picture is much more detailed that a regular x-ray picture and does not involve any radiation exposure. An instrument that sends high frequency sound waves is placed on your ribs near the breast bone directed toward your heart.
- MUGA Scan: A radioactive tracer is injected via IV (intravenous catheter) which attached to blood cells. Then an instrument is used to see inside your heart.
- CT scan - an x-ray machine that makes computerized pictures of the inside of your body.
- CT scan with contrast: A dye will be injected via a needle into your body. An x-ray machine that makes computerized pictures of the inside of your body.
- Dexa Scan: A bone mineral density scan is a specialized x-ray test that measures the amount of calcium in the spine and hip. It is a non-invasive procedure and it takes about 15 - 30 minutes.
- Blood transfusion
- Skin Photography: Describe exactly what will be photographed.
- HIV/Hep B/C Screen: Include the following statement: “Positive test results are reportable to local health authorities”.
- Videography (e.g. Parkinson’s symptoms): Describe exactly what will be videotaped
- Questionnaires
- A pulmonary function test: A group of tests will be performed to measure how well your lungs take in and let out air and how well they move oxygen into your blood
- Biomarker (biological flags used to measure disease progress or drug effect): describe what will be done (e.g. blood draw).
- Mandatory tissue sampling: Describe the type, the method, the amount, and any conditions that may apply.
- Optional tissue sampling (provide a separate consent form for each): future banking, pharmacogenetic (genetic characteristics in an individual used to measure disease progress or drug effect) or pharmacogenomic (genetic characteristics in a population/group used to measure disease progress or drug effect).
13.8. To improve readability of the Form, consider including a study chart to facilitate visual presentation of what will be done when (see below example):

**Summary of Tests and Procedures**

Example for a non-complicated schedule:

<table>
<thead>
<tr>
<th>Visit</th>
<th>Tests and Procedures (as applicable based on the protocol)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening</td>
<td>Routine blood tests, complete questionnaire, sample collection.</td>
</tr>
<tr>
<td>Visit 1 <em>approx visit length</em></td>
<td>Begin study drug</td>
</tr>
<tr>
<td>Visit 2 <em>approx visit length</em></td>
<td>Blood tests</td>
</tr>
<tr>
<td>Visit 3 <em>approx visit length</em></td>
<td>Blood tests</td>
</tr>
<tr>
<td>Visit 4 <em>approx visit length</em></td>
<td>Blood tests</td>
</tr>
<tr>
<td>Visit 5 <em>approx visit length</em></td>
<td>Blood tests and exams. 2nd chest x-ray for research purposes</td>
</tr>
</tbody>
</table>

Example for a more complicated schedule (e.g. clinical trials):

<table>
<thead>
<tr>
<th>Tests</th>
<th>Visit 1 /Week</th>
<th>Visit 2/Week 4</th>
<th>Visit 3/Week 8</th>
<th>Visits 4–10 every month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood tests</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CT scan</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Questionnaire</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research blood tests</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length of visit</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

13.9. The [insert study drug/intervention] [will/will not - choose one] be available after study is complete.

14. **Mandatory Sample Collection**

Describe the mandatory sample collection, including the sample type and amount and manner/safety of acquisition, purpose of the research (including any commercial use), measures
employed to protect privacy and minimize risk, and length, method, and location of storage. See suggestions below, or revise as applicable to the research.

Example wording:

The researchers doing this study need to do tests on samples (described below) to insert study-specific LAY explanation of the research purposes for all samples collected.

The collection of these samples is a necessary part of this study. Samples will be used only for these purposes. The samples will not be sold.

Specify what will happen to samples once the mandatory research has been completed. For example:
Once these tests have been completed, any leftover samples will be returned to the facility from which they were obtained if needed or destroyed include the following if applicable unless you wish to give permission for other future research purposes, in which case you will be given a separate optional consent form to sign.

Include one of the following options:
Hereditary genetic testing (to look at whether specify condition runs in families) will not be done on these samples.
Or
Hereditary genetic testing (to look at whether specify condition runs in families) will/may be done on these samples

If there is a possibility that a medically relevant sample will be exhausted:
If you participate in this study it is possible that there will not be enough of your tissue sample left for other testing that may need to be done in the future. Please speak to the study doctor to discuss this possibility.

Describe who will be informed of the results of the mandatory research. For example:
Reports about any research tests done with your samples will not be given to you, the study doctor(s) or study staff, your doctor, or other health care provider(s). These reports will not be put in your medical records.
Or
Reports about research tests done with your samples will be given to the study doctor(s). If you would like to learn the results of this research, please let them know.

Tissue Collection (Required)
Describe the method of tissue sample collection and associated risks. Specify the location and purpose for the review. See example text below, or revise as applicable to the research
Example wording:

A small sample of your tissue that has already been removed by a previous surgery or biopsy will be obtained by the researchers doing this study. No further surgeries or biopsies are required of you for this purpose. If applicable, explain whether they may still participate if a sample is not available or whether a fresh tissue sample will then be required – see below.

If a fresh tissue sample is required
As part of this study, you will 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 your insert tissue type e.g., liver. Explain in lay language whether this will be done using a local or general anesthetic and whether overnight hospital stay may be required. Include information about risks in the Risks section.

Identify location where specimens will be retained. For example:
These tissue samples will be sent to a laboratory at insert location where they will be examined.

Blood/Urine Collection (Required)
Describe the method of blood/urine/other sample collection and associated risks. Specify the location and purpose for the review. See example text below, or revise as applicable to the research

Urine will be collected Specify number of samples to be collected and timing (e.g., specify if 24 hour collection) if multiple samples are required. These urine samples will be sent to a laboratory at the insert location where they will be examined.

Blood samples will be taken by inserting a needle into a vein in your arm. These will be taken at the same time as your study related tests whenever possible, describe sample timing e.g. at entry to the study and <X> weeks after you stop the study intervention. Specify amount of blood to be collected and timing if additional samples are required and the tests to be done on these samples. These blood samples will be sent to a laboratory at the insert location where they will be examined.

How will samples be identified?
To protect your identity, the information that will be on your samples will be limited to specify which identifiers will be on the sample(s). If additional personal information is also being provided to the laboratory (e.g., on additional forms provided with the review materials), include a description of the information provided, e.g., The laboratory will also receive information containing your…

Despite protections being in place, there is a risk of unintentional release of information. Due to technological advances in genetics, there may be a risk that the genetic information in the samples could be linked back to you.
Can I withdraw these samples?
Describe the process for withdrawal of samples, and any limitations to the withdrawal. See the suggested text below, or revise as applicable

If you no longer want your samples to be used in this research, you should tell specify appropriate contact role, who will ensure the samples are describe what will happen to samples if participant withdraws consent, e.g., returned to the hospital from which they were obtained or destroyed.

Describe any limits of the withdrawal, if applicable. For example:
If tests have already been done on your sample(s) it will not be possible to withdraw those results. However, no further testing will be done.

If samples will be anonymized at a certain point
You can request withdrawal of your specimens until insert expected anonymization point, when the samples will be made anonymous. It won’t be possible to return samples after this because the researchers will not know which sample is yours.

State whether or not the participant may continue to participate in this main part of the study, if they withdraw these required samples.

Optional Research

The Researchers doing this study are interested in doing additional optional research. You will be given an additional optional study consent form to read and sign if you wish to give permission for this. You may decide not to participate in the optional research and still participate in this main study.

15. What are the responsibilities of study participants?
List participant responsibilities and other important instructions participants should keep in mind during the study.

15.1. Include only those relevant to your protocol.
15.2. It is important to determine if participants are already part of an ongoing study and may be compromised by participation in this study.

Example: If you are participating in another study, please inform the study doctor or nurse to see if you are eligible to participate in this study.

16. What are the risks and harms of participating in this study?

16.1. Study Related Side Effects

Include a list of all study related side effects (physical and psychological). See list of standard wording below (13.10).
Address psychological risks such as anxiety, distress, embarrassment, or feelings of sadness that may arise from questionnaires and interviews about sensitive issues (e.g. mental health, sexuality).

16.2. **Standard of Care Side Effects** (optional)

It is not necessary to describe, in detail, the risks of the standard procedures that participant would undergo even if he/she was not a research participant.

16.3. **Frequency & Severity of Side-Effects**

List the frequency and severity of side effects. Side effects that have not been clearly linked to the study drug should also be included.

For example: Increases and decreases in blood pressure have been noted in some patients receiving the study drug but it is not clear whether these effects are truly related to the study drug.

Below is a guideline to aid you in determining the appropriate category to enter side effects for your study. Provide lay explanations. **Include an upper limit for each percentage range.**

- **Very likely/Common (Occurs 50 to 100%):**
  - [...] 
- **Likely/Common (20 to 49%):**
  - [...] 
- **Less Common (1 to 19%):**
  - [...] 
- **Rare (less than 1%):**
  - [...] 
- **Rare but Serious (less than 1%):**
  - [...] 

16.4. **Studies in the early phase of development**

The investigational drug [name of 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 [list as per Investigator Brochure]. There may be additional risks and side-effects that are currently unforeseen and therefore not listed in this study information and consent form.

**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:**

As of [date], only [n] people have been given this drug and the side effects that have been reported are: [specify - examples]:

- n experienced headaches
• n experienced diarrhea

It is not yet known if these side effects are caused by [study drug name] or how likely these side effects will be. There also may be other side effects not yet known.

16.5. Separate side effects of each drug and procedure as appropriate.

16.6. Use plain language to describe or explain.

Examples of unacceptable language in the risks include: “punctate subepithelial, corneal opacity, low lymphocytes, hypertension, myocardial infarction, edema etc.”

16.7. Explain the significance of a side effect if it is not obvious.

Example: Low white blood cells may decrease your ability to fight infection or may increase your ability to get a new infection.

Address reversibility of side effects, long term side-effects as applicable and any treatments, interventions or precautions that may be taken to address these risks.

16.8. Interactions/Contraindications with Contraception Methods. If applicable, insert:

[Known interactions or contraindications with specific contraception methods]

16.9. The HSREB requires that potential study participants be presented with accurate and meaningful information that enables them to make an informed decision whether to participate in a study. Therefore, the Consent document must present frequency of side effects of all drugs used in a study (regardless of the Phase of the study) when data are available.

Please ensure that there is upper and lower bounds; e.g., “>10 % of patients” is not sufficient information for study participants.

Rationale: The statement ">10%" is meaningless to potential participants. It is not clear if this 10-100% of patients having experienced a specific adverse event has an emphasis on 10% of patients or 100%. This difference could affect a potential participant’s decision to participate in the research study. There is a big difference between 10% and 100%. Therefore, the REB requests the sponsor to be more specific. For example, 10-50% or 50-100% or even 1 out of 10 patients or 1-1000 patients, etc

17. What are the reproductive risks?

Risks Related to Pregnancy

Breastfeeding warning, if applicable:

The drugs or procedures used in this study [might be/are known to be] harmful to an unborn baby or sperm. Women should not breastfeed while on this study because the drugs used in this study might be present in your breast milk and could be harmful to your baby.
Pregnancy follow-up, if applicable:
If the sponsor would like to follow the pregnancy of a participant and its outcome. Also include information that should pregnancy occur, and they agree to be followed, the female partner will be asked to sign a separate consent form.

If applicable, insert:
If you are a woman and can have children, you will need to have a pregnancy test before enrolling in the study to be sure that you are not pregnant. If you are pregnant, you cannot participate in this study. You must not become pregnant or father a baby while on this study [and for ## months afterward] because the drugs or procedures used in this study might be harmful to an unborn baby. Your study doctor should discuss methods with you to ensure that you do not become pregnant or father a baby during the study. Your study doctor will be able to inform you of methods that are safe to use while on this study. If you do become pregnant during the study or if you father a child during the study you should immediately notify your study doctor.

Becoming Pregnant During Study. If applicable, insert:
The risk to your partner and the fetus is unknown. If your partner becomes pregnant, she will be asked to sign a consent form to allow access to information on the outcome of her pregnancy. If your partner does not consent to this, it will not affect your continued involvement in the study.

Potential Loss of Ability to Conceive. If applicable, insert:
Some of the drugs used in the study may make you unable to have children in the future. Your study doctor will discuss this with you.

18. What are the benefits?
18.1. Identify benefits to participants.
18.2. If study treatment is involved no beneficial effects are to be guaranteed.
18.3. If no direct benefit to participant is anticipated include a statement to that effect.
18.4. If there are potential benefits, describe as completely as possible.
18.5. An additional sentence/paragraph about the possible benefits to society or science may also be inserted. This should be separate from the specific benefits
18.6. Monetary compensation is NOT a benefit.
18.7. If applicable, insert:
You may not receive direct benefit from being in this study. Information learned from this study may help lead to improved treatment of [insert the disease/reason for the study] in the future.
18.8. If applicable, insert
There are no known benefits to you associated with your participation in this research study.
19. Can participation in this study end early?
19.1. Include information on stopping rules and when researchers may remove participants from the clinical trial without the participant’s consent.

19.2. If there are foreseeable circumstances and/or reasons under which the participant's participation in the study may be terminated without the participant’s consent include this information.

20. What other choices are there?
20.1. Include applicable information on alternative procedures or courses of treatment that may be available to the potential participant should they choose not to participate or if they withdraw from the study. It is not enough just to indicate that there are alternatives, they must be described.

Examples:

If you decide not to participate or if you withdraw from the study before it is completed, the alternative procedures or course of treatment will be…

If no alternatives exist:

An alternative to the procedures described above is not to participate in the study and continue on just as you do now.

21. What are the rights of participants (including in the event of a study related injury)?

The following statements are examples of acceptable language (if any of the below are used, ensure the statement is applicable to your study):

- If you are harmed as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost.
  
  You do not waive any legal rights by signing the consent form.

- If you become ill or injured as a direct result of taking the study drug while participating in the study, the Sponsor will assist you by paying for any treatments you may need according to the current medical practice that is not covered by healthcare insurance.
  
  You do not waive any legal rights by signing the consent form.

- If you have an injury, illness, or adverse event (side effect) as a direct result of your participation in this study, [Sponsor/Researcher/Institution Name] agrees to pay reasonable medical expenses necessary to treat the injury; provided you have followed the directions of the study doctor and to the extent you are not otherwise reimbursed by public Health Care System or personal medical insurance.
  
  You do not waive any legal rights by signing the consent form.

- If you require treatment for any injuries or illness directly related to procedures required by the study, or if you suffer side effects while on study medication, you should contact
your study doctor as soon as possible. The necessary medical care will be provided to you at no additional cost to you.

You do not waive any legal rights by signing the consent form.

You must include the following statement:

- You do not waive any legal right by signing this consent form

This section should not have any suggestive language that a patient's rights to care could potentially be compromised in the event of study related injury.

**Examples of Unacceptable Sponsor Wording:**

- “For subjects treated according to the protocol, you will be covered by insurance held by the sponsor for medical costs arising from any study-related injury.”

- “If you suffer any side effect or other physical injury resulting directly from the study drug, the Sponsoring Company will pay for the reasonable costs of medical treatment to the extent permitted by the law of your country if:
  - You took the study drug as directed by the Study Doctor your injury was not deliberately caused.
  - The Study Doctor was immediately notified about your injury, and the medical advice of the Study Doctor was followed.”

The above statements and similar statements will not be approved for the following reasons:

- The word "protocol" is not meaningful to patients because patients do not have access to the protocol. Therefore, it is not accurate to refer to it.

- The above statements suggest a participants rights to care could potentially be compromised in the event of study related injury.

- Protocol Deviations may occur during a study. Since deviations are procedures that occur "NOT according to the protocol" the Sponsor is suggesting that patients are held responsible for actions that may be outside the control of the patient. Therefore, in the event of a protocol deviation resulting in a negative consequence or harm to the patient, someone (not the patient) needs to be held responsible. (That someone would be the Sponsor or the Site - this must be dealt with at the contract level, not the consent form level).

- Due to the nature of harm, the study doctor cannot always be notified immediately

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**22. What are the costs to participants?**

You will not have to pay for any of the [procedures/study drug/intervention] involved with this study. You [will be reimbursed/will not be reimbursed “$X”] for [transportation, meals, time, inconvenience].

**22.1. Include whether participants will incur any expenses as a result of their participation in the study. Include any reimbursement (e.g., parking), gifts in-kind, vouchers, etc.**
participants and how reimbursement will be pro-rated if participants withdraw early from study.

22.2. Specify any additional costs to the participant that may result from participation in this study that will not be reimbursed.

22.3. Indicate whether the cost of background drugs or drugs given in combination is included or whether the participant will have to pay for them. List drugs they will have to pay for.

23. Are participants paid to be in this study?

23.1. Include Information about any payments, including incentives for participants and reimbursement for participation related expenses

23.2. If for example gift cards will be given to participants do not include the company name as the endorsement of a company is not acceptable.

24. Can participants choose to leave the study?

24.1. If the researcher decides to withdraw you from the study

The Researchers can take you off the study drug early for reasons such as:
[List reasons based on your protocol]

24.2. If you request to be withdrawn from the study

Insert information on the participant’s right to request the withdrawal of data and/or human biological materials, including any limitations on the feasibility of that withdrawal.

2.2 If the sponsor will allow the participant to have their data withdrawn when the participant withdraws from the study, insert the following:

Data:
If you decide to withdraw from the study, you have the right to request withdrawal of information collected about you. Let your study doctor know.

Studies involving tissue/blood/body fluids:
If you decide to withdraw from the study, you have the right to request withdrawal of your information and [insert types of samples as applicable to study such as blood, tissue, etc]. Let your study doctor know.

2.3 If the study site will continue to use the participants data after they have withdrawn from the study:

Data:
If you decide to withdraw from the study, the information that was collected before you leave the study will still be used in order to help answer the research question. No new information will be collected without your permission.
Studies involving tissue/blood/body fluids:
If you decide to withdraw from the study, you have the right to request withdrawal of your [insert types of samples as applicable to study – e.g. blood, tissue, etc]. Let your study doctor know. However, after these records linking your identity to your sample are destroyed, it will no longer be possible for [sponsor] to discard your sample if you withdraw your consent. [Sponsor Name] will keep and use any research results that we obtain prior to your withdrawal of consent.

24.3. A study participant may not always provide a written request to withdraw from a study. This may be due to illiteracy, being lost to follow up, and/or verbally informing the study doctor that they will no longer participate. It is the responsibility of the researcher to notify the sponsor. An explanation of this in this section is required.

24.4. Do not include any Sponsor contact information. The participant should never contact the Sponsor directly to withdraw. The participant’s identifiable information should remain with the study doctor. The participant should only contact their study doctor to withdraw.

25. How will participant’s information be kept confidential?

25.1. Describe the protection of the participant’s privacy, method of storing research data, and who all will have access to the information collected for the study. Ensure that it is clear who has access to what type of information.

25.2. Include the type of personal health information (PHI) that will be collected (e.g., name, address, date of birth (specify partial or full), new or existing medical records, etc.). PHI should be collected at the lowest level of identifiably possible and only kept as long as necessary.

25.3. If PHI is not being collected but rather Personal Information (e.g. participants are health care professionals or caregivers, students) language for this section should be adjusted appropriately.

25.4. Indicate if people/groups/organizations outside the study team will have access to information collection.

Qualified representatives of the following organizations may look at your medical/clinical study records at the site where these records are held, for quality assurance (to check that the information collected for the study is correct and follows proper laws and guidelines).

Examples include:

- Representatives of Lawson Quality Assurance Education Program
- Representatives of the University of Western Ontario Health Sciences Research Ethics Board that oversees the ethical conduct of this study.
- [Sponsor Name], and its affiliated companies [include and specify a CRO if applicable]
• Representatives of Health Canada or other regulatory bodies (groups of people who oversee research studies) outside of Canada, such as the United States Food and Drug Administration.

• LIST other regulatory authorities (because they oversee the use of drugs/device in other countries)

25.5. The document should not contain language that may be construed as requiring the participant to consent to unrestricted access to his or her medical records by third parties.

25.6. If there IS a sponsor include the following information:

• Indicate if any study information will be sent outside the institution to the Sponsor.

• Include a statement that any information about them that is sent out of the institution will have a code and will not show any information that would directly identify them.

• Include a statement that the Sponsor may use the study information and share it with its partner companies (ensure that these companies are disclosed) or with national and international regulatory agencies to help answer the study question, to get approval to sell [insert study drug/device name/intervention], to develop future studies on this product or for research related to this study.

25.7. If information will be released to any other party for any reason,

2.2 state the person/agency to which the information will be provided,

2.3 the nature of the information,

2.4 the purpose of the disclosure and,

2.5 include a statement that any information about them that is sent out of the institution will have a code and will not show any information that would directly identify them.

25.8. If identifiable information will be shared with others outside the study team please clarify what information will be disclosed and with whom it will be shared.

Note: If there is planned disclosure of personal identifiers, or if they are used on any research-related information/documents, or if they are part of the unique identifier, this must be justified in the REB application and approved.

25.9. If this is a Health Canada regulated study, insert the following:

The study doctor will keep any personal health information about you in a secure and confidential location for a minimum of 25 years as required by Canadian law. A list linking your study number with your name will be kept by the study doctor in a secure place, separate from your study file.

If it is NOT a Health Canada regulated study, insert the following:

The study doctor will keep any personal health information about you in a secure and confidential location for a minimum of [##] years. A list linking your study number with
your name will be kept by the study doctor in a secure place, separate from your study file.

25.10. If applicable, indicate whether information collected for the study [will/will not] be recorded in their medical record.

25.11. Include a statement that all information collected during this study, including their PHI, will be kept confidential and will not be shared with anyone outside the study unless required by law.

25.12. Include a statement that participants will not be named in any reports, publications, or presentations that may come from this study.

25.13. If applicable insert: Your family doctor will be informed that you are taking part in a study so that your study doctor and your family doctor can provide proper medical care.

25.14. If an autopsy report is being provided to the sponsor, include the following:

This clinical study does not require that an autopsy be performed. However, in the event an autopsy is performed and a copy of the autopsy report is provided to the study doctor, this report will be sent to the study sponsor as part of the information collected for the clinical study. Your name, date of birth, address, telephone number, and other information that could identify you will be removed from the autopsy report before it is sent to the study sponsor. The autopsy report will only be sent to the study sponsor provided that you indicate your consent by signature below and your highest level of personal representative, family, or next of kin (as determined by hospital policy) also consents.

26. Will information about this study be available online?

The following statement shall be provided to each clinical trial to each clinical trial participant:

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

*Mandatory for inclusion, verbatim, in US FDA regulated clinical trials

27. Commercialization

[Sponsor name] and/or others intend to claim sole ownership of any research results consistent with this consent. By signing this consent, you agree that [Sponsor name] can apply for patents and you will not receive any financial benefit that might come from the research.

28. Whom do participants contact for questions?

28.1. Instructions on whom (name and phone number) to contact regarding any questions or concerns that may be raised by participating in the study or questions that may be raised by being a research participant. The 24 hour contact number can be repeated here if determined to be needed for the study (e.g. blinded study).
You must also include:
If you have any questions about your rights as a research participant or the conduct of this study, you may contact The Office of Research Ethics (519) 661-3036, email: ethics@uwo.ca.

Or

If this is a Lawson Health Research study:
If you have any questions about your rights as a research participant or the conduct of this study, you may contact Dr. David Hill, Scientific Director, Lawson Health Research Institute (519) 667-6649.

29. Consent
Include this section with the rest of the LOI document, but on its own page.

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to take part in this study.

WHEN YOU INTEND TO RECONTACT FOR FUTURE RESEARCH
If you wish to ask participants to consent to future contact for additional studies, please provide check boxes before the “Participant’s Signature” block for participants to accept or decline to be contacted for other studies in the future. See example below:

CONTACT FOR FUTURE STUDIES
Please check the appropriate box below and initial:
___ I agree to be contacted for future research studies
___ I do NOT agree to be contacted for future research studies

__________________
__________________
Print Study Participant’s Name Signature Date (DD-MMM-YYYY)

My signature means that I have explained the study to the participant named above. I have answered all questions.

__________________
__________________
Print Name of Person Obtaining Consent Signature Date (DD-MMM-YYYY)

If you are including people who require a substitute decision maker, insert the following:

☐ Your signature on this form indicates that you are acting as a substitute decision maker(s) for the participant and the study has been explained to you and all your questions have been
answered to your satisfaction. You agree to allow the person you represent to take part in the study. You know that the person you represent can leave the study any time.

<table>
<thead>
<tr>
<th>Print Name of Substitute Decision Maker</th>
<th>Signature</th>
<th>Date (DD-MMM-YYYY)</th>
</tr>
</thead>
</table>

Relationship to Participant

If you are including people with communication difficulties, insert the following:

Was the participant assisted during the consent process? □ YES □ NO

If YES, please check the relevant box and complete the signature space below:

☐ The person signing below acted as a translator for the participant during the consent process and attests that the study as set out in this form was accurately translated and has had any questions answered.

<table>
<thead>
<tr>
<th>Print Name of Translator</th>
<th>Signature</th>
<th>Date (DD-MM-YYYY)</th>
</tr>
</thead>
</table>

Language

If you are including illiterate people (those who cannot read English, add the following):

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and has had any questions answered.

<table>
<thead>
<tr>
<th>Print Name of Witness</th>
<th>Signature</th>
<th>Date (DD-MM-YYYY)</th>
</tr>
</thead>
</table>

Relationship to Participant