

Guidance Document	HSREB Main Consent Form
Effective Review	Delegated & Full Board
Version Date	14 August 2020

<p>Legend</p> <hr/> <p>Blue text: Guidance and/or instructions Black text: Suggested wording and/or example Red text: Language that should not be included</p>
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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 clinical trial, 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.

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/Funder 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. Conflict of Interest

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. 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. 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

The **insert recipient of funding** e.g., **hospitals** is receiving financial payment from **[insert Sponsor/Funder]** to help offset the costs of conducting this research.

The doctor treating you also may be the doctor in charge of the study.

8. 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].

- 8.1. 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>).

9. Why is this study being done?

9.1. Provide background information on what prompted the need for this study

9.2. Explain the purpose of the study in lay terminology

Explain the purpose of the study, using suggestions below as applicable:

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.**

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

10.1. 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.

10.2. 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.

11. What will happen during this study?

11.1. Assignment to a group

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., 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.

Explain 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 clinical trials 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.

11.2. Inclusion/Exclusion Criteria (optional)

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

11.3. 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.”

12. 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:

12.1. Present procedures in bullet format

12.2. 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.

12.3. 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.

12.4. 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.

12.5. Number of study visits

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

12.6. 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.

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

Clarify between experimental procedures or medical tests (e.g., being tested as part of the research) from any standard procedures.

Explain any risks of experimental procedures and medical tests in the risk section

Experimental Procedures

The following test(s) is/are considered experimental and will only be done for participants on this study:

List the procedures and tests. Include explanation of what each test involves and the purpose/reason/rationale for including it in the research.

If focus groups are a mandatory component of the research, include the following section.

Focus Group

You will be asked to attend **specify how many focus group(s) if more than one focus group, provide information about timing e.g., before you begin the study and then every X weeks/months.** A focus group is a small group of representative people who are asked to speak about their opinions as part of the research. A moderator will organize the focus group(s). Each focus group discussion will be about **specify length in minutes or hours in length and will take place specify location.** You will be asked to speak **about explain topics of discussion e.g., your experiences with condition/intervention.** Specify if there is any recording device(s) used e.g., **The focus group sessions will be audio taped.**

While the study team will take precautions to protect your confidentiality we cannot guarantee that other members of the focus group will respect your privacy or keep the discussions of the group confidential.

If questionnaires are a mandatory component of the research, include the following section:

Questionnaires

You will be provided with a questionnaire **provide information about the timing of questionnaires e.g., before you begin the study and then every two weeks for a year.** The purpose of the questionnaire is **include description of purpose e.g., to understand how the study intervention and illness affects your quality of life.** Each questionnaire will take about **indicate estimated time to complete in minutes to complete.**

The information you provide is for research purposes only. Some of the questions are personal. You can choose not to answer questions if you wish.

If the questions are of a sensitive nature, explain that they might experience emotional distress, explain what should they do and what type of help will be provided if this happens.

If questionnaires include medically relevant information, but won't be reviewed, include the following:

Even though you may have provided information on a questionnaire, these responses will not be reviewed by your health care team or study team - if you wish them to know this information please bring it to their attention.

If participant diaries are a mandatory component of the research, include the following section.

Participant Diaries

Inform the participant of the expectations associated with the participant diary. See suggested text, or revise as applicable to the research

You will be asked to keep a diary of when you identify e.g., take your study medication. Please record identify what is being recorded e.g., the exact time of taking each dose every day. You will be asked to return the diary to this centre.

If central review is a mandatory component of the research, include the following section.

Central specify type of review e.g., Radiology/Radiotherapy/Surgical Review

If the research involves centralized off-site review, include this section. Provide a description of the material(s) being reviewed centrally, including the type, reason, location, retention and identifiers. See suggested text below or revise as applicable to the research

Specify material being submitted e.g., Copies of your CT scans/Surgical specimens will be collected as part of this study. This is required for include description of rationale, e.g., quality assurance and data management. The copies will be sent to specify location conducting review, and kept until the end of the study monitoring period or specify other retention period

- 12.8. 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:

Visit	Tests and Procedures <i>(as applicable based on the protocol)</i>
Screening	Routine blood tests, complete questionnaire, sample collection.
Visit 1 <i>approx visit length</i>	Begin study drug
Visit 2 <i>approx visit length</i>	Blood tests

Visit 3 <i>approx visit length</i>	Blood tests
Visit 4 <i>approx visit length</i>	Blood tests
Visit 5 <i>approx visit length</i>	Blood tests and exams. 2nd chest x-ray for research purposes

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

Tests	Visit 1 /Week	Visit 2/Week 4	Visit 3/Week 8	Visits 4-10 every month
Blood tests				
CT scan				
Questionnaire				
Research blood tests				
Length of visit				

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

13. 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.

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

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.** This procedure has risks such as specify risks, e.g., blood loss, pain and rarely an infection at the biopsy site.

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.

14. What are the responsibilities of study participants?

List participant responsibilities and other important instructions participants should keep in mind during the study.

- 14.1. Include only those relevant to your protocol.
- 14.2. 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.

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

15.1. Study Related Side Effects

Include a list of all study related side effects (physical and psychological).

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).

15.2. 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.

15.3. 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%):

- [...]

15.4. 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.

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

15.6. 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.”

15.7. 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.

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

[Known interactions or contraindications with specific contraception methods]

15.9. 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%.

16. What are the reproductive risks?

Risks Related to Pregnancy

If there are known interactions or contraindications with specific methods, they should be included in the consent form.

Breastfeeding warning, if applicable:

The drugs or procedures used in this study [might be/are known to be] harmful to an unborn baby (fetus) 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.

St. Joseph Health Care Hospital is a Catholic health care organization.

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.

Partner Becoming Pregnant During Study. If applicable, insert:

The risk to your partner and the unborn baby (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.

17. What are the benefits?

- 17.1. Identify benefits to participants.
- 17.2. If study treatment is involved no beneficial effects are to be guaranteed.
- 17.3. If no direct benefit to participant is anticipated include a statement to that effect.
- 17.4. If there are potential benefits, describe as completely as possible.
- 17.5. An additional sentence/paragraph about the possible benefits to society or science may also be inserted. This should be separate from the specific benefits
- 17.6. Monetary compensation is **NOT** a benefit.
- 17.7. 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.

- 17.8. If applicable, insert

There are no known benefits to you associated with your participation in this research study.

18. Can participation in this study end early?

- 18.1. Include information on stopping rules and when researchers may remove participants from the clinical trial without the participant's consent.
- 18.2. Identify reasons why participants may be taken off the study. Examples are outlined below. Include or modify bullets below as applicable:
 - The study intervention does not work for you
 - You are unable to tolerate the study intervention
 - You are unable to complete all required study procedures
 - New information shows that the study intervention is no longer in your best interest
 - The study doctor no longer feels this is the best option for you
 - The Sponsor decides to stop the study
 - The Regulatory Authority/ies (for example, Health Canada) or research ethics board withdraw permission for this study to continue
 - Your group assignment becomes known to you if applicable or others (like the study doctor or study staff)
 - If you plan to or become pregnant

If this happens, it may mean that you would not receive the study intervention for the full period described in this consent form.

If you are removed from this study, the study doctor will discuss the reasons with you and plans will be made for your continued care outside of the study.

19. Voluntary Participation

- 19.1. 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.

- 19.2. 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”.

- 19.3. 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.

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 withdrawal 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.

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

22. What are the costs to participants?

Inform the participant of any anticipated expenses associated with participation in the clinical trial

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. to 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 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. It is important to note that a record of your participation must remain with the study as such, the researchers may not be able to destroy your signed letter of information and consent, or your name on the master list, however any data and/or samples may be withdrawn. 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. 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.
- 25.2. 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.
 - 2.2 Do not include any information regarding the use of patient finding/locator services. The REB will not approve the use of these services once a participant has withdrawn, completed, or been removed from the study.
- 25.3. 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.
- 25.4. Indicate if people/groups/organizations outside the study team will have access to information collection.

Authorized representatives of the following organizations may look at your original (identifiable) medical/clinical study records at the site where these records are held to check that the information collected for the study is correct and follows proper laws and guidelines. They may also be given remote access to these records through the internet via secure video conference or through redacted (personal identifiers blacked out) copies

Examples include:

- Representatives of Lawson Quality Assurance Education Program
- Representatives of Western University and its Health Sciences Research Ethics Board that oversees the ethical conduct of this study.

Insert, if applicable (e.g. If there is a sponsor):

- *[Sponsor Name]*, and its affiliated companies *[include and specify a CRO if applicable]*

Insert, if applicable (e.g. Health Canada Regulated):

- 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. **Data Retention:**
- The study doctor will keep any personal health information about you in a secure and confidential location for [##] 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.
- NOTE:**
Lawson's data retention policy: 15 years
Western's Faculty Collective Agreements Research data retention policy: 7 years
Health Canada's data retention policy: 25 years
- 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 identifiable information collected during this study 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. **Re: Use of external database or third party reimbursements**

If researchers will be using any of the following, you will need to review Appendix A for further information:

1. EmPower database.
2. Cambridge Brain Sciences (CBS) Website.
3. Use of third party reimbursements – use of an external company to provide compensation directly to study participants.

25.15. **Re: open access data:**

If you anticipate data may be made available to journals and/or other researchers (e.g., for replication studies and/or re-analysis for different research questions) then participants must be informed of this in the Letter of Information and Consent (LOI/C), as well as what type of information will be shared. NOTE: Indicating that all information will be kept confidential to the researchers will restrict you from sharing this information (even if anonymized) outside of the research team in the future.

Examples:

CLINICAL DATA

For the reasons of transparency and education, it is strongly encouraged by many medical journals and other authorities to publish the anonymized data from clinical studies for public use (anonymized means no data which can identify you would ever be published). This data is visible to researchers or the general public after the study is over. Researchers may use this data to improve knowledge about [\[insert topic here\]](#).

We will publish the anonymized data from this study. [\[Consider including some examples of what anonymized data would like like.\]](#) You should note that there will be NO personal identifiers, such as your [\[insert as appropriate: name, address, date of birth, etc.\]](#) in this list. Nothing in published dataset would ever identify you specifically. There are guidelines for publishing safe, anonymized data and the researchers will be following these.

[\[insert sample table of anonymized dataset for participants' information\]](#)

If you are interested in the background behind Open Data, we invite you to start at the British Medical Journal's Open Data website at: www.bmj.com/open-data"

OTHER QUANTITATIVE DATA

All identifiable information will be deleted from the dataset collected so that individual participant's anonymity will be protected. The de-identified data will be accessible by the study investigators as well as the broader scientific community. More specifically, the

data [will/may be posted on specific database OR made available to other researchers upon publication] so that data may be inspected and analyzed by other researchers. The data that will be shared on [insert database/publication] will not contain any information that can identify you.

See [Open Access Guidance Document](#) for more information.

25.16. When Autopsy reporting is requested (suggested wording includes):

This clinical study does not require that an autopsy be performed. However, in the event an autopsy is performed, a copy of the autopsy report, if available to the study's Principal Investigator, 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. What if Researchers Discover Something about a Research Participant?

If incidental findings are anticipated as a result of the study, include the following section and address what information will be provided to participants.

During the study, the researchers may learn something about you that they didn't expect. For example, the researchers may insert anticipated incidental findings e.g. find out that you have another medical condition.

Describe anticipated management plan. For example:

If any new clinically important information about your health is obtained as a result of your participation in this study, you will be given the opportunity to decide whether you wish to be made aware of that information.

29. Whom do participants contact for questions?

- 29.1. 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 Human Research Ethics (519) 661-3036, 1-844-720-9816, email: ethics@uwo.ca. The REB is a group of people who oversee the ethical conduct of research studies. The HSREB is not part of the study team. Everything that you discuss will be kept confidential.

Or

If this is a study that requires Lawson oversight:

The Letter of Information should include the following language for St. Joseph's Health Care London as a contact outside of the research team:

If you have any questions/concerns about your rights as a research participant or the conduct of this study, please contact: St. Joseph's Health Care London Patient Relations Consultant at 519-646-6100 ext. 61234.

The Letter of Information should include the following language London Health Science Centre as a contact outside of the research team:

If you have any questions about your rights as a research participant or the conduct of this study, you may contact the Patient Relations Office at LHSC at (519) 685-8500 ext. 52036.

30. Consent

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

Include the Study Title

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.

Print Name of Participant
MMM-YYYY

Signature

Date (DD-

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

The person obtaining consent must also sign the consent form. Please insert the following:

)

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.

Print Name of Substitute Decision Maker Signature Date (DD-*MMM*-YYYY)

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.

Print Name of Translator

Signature

Date (*DD-MMM-YYYY*)

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.

Print Name of Witness

Signature

Date (*DD-MMM-YYYY*)

Relationship to Participant

Appendix A:
Guidance on wording for databases and third party reimbursements

For researchers who would like to use EmPower Database:

The data that is collected from you is managed by a company called EmPower Health Research. Any information provided by you is protected by a username and password. It travels in a scrambled format to a server (storage computer) that is located in Montreal, Canada.

Your [<please identify all identifying information to be stored in EmPower>](#) email address, and your full date of birth are part of this database.

The database will send automatic reminder emails to you if you are required to login and answer questions. Instructions for logging into the database will be provided by the research assistant. The company that houses the database is a professional company with extremely high standards of physical and virtual security. We want to let you know however, that even with this high level of security, there is always a remote chance that your information could be accessed or “hacked” by someone who is not supposed to have your information. If we became aware that this had happened, we would inform you immediately.

We wish to also make you aware that Dr. Bryant, who is one of this study's investigators, is the Owner and Director of EmPower Health Research Inc. However, Dr. Bryant does not receive any personal gain or compensation of any kind due to the use of EmPower services on this study.

NOTE to researchers: As a reminder, only the minimal personal identifiers should be collected when required. Just because an identifier was collected in one study does not mean it should be collected for another as it might not be necessary and justified. If it is necessary it needs to be sufficiently justified (a response that it has always been collected is not a justification) and this must be approved by the REB.

For researchers who would like to use Cambridge Brain Sciences (CBS) Website

[If researchers are providing fake email addresses to their participants to access CBS please include the following:](#)

To access the Cambridge Brain Sciences (CBS) website the researchers of this study will provide you with a random identifier, for example ‘abc123’ instead of using your personal email. No other personal information will be collected **OR**

the following identifiers will be collected [<insert which identifiers the researchers may collect>](#).

[If researchers expect participants to use their personal email address to access CBS:](#)

You will be asked to create an account on Cambridge Brain Sciences (CBS) using your personal email address. CBS will store this email address along with the following identifiers <insert which identifiers the researchers may collect> **OR**

... and no further personal information will be collected.

You must also include:

It is also important to note that Cambridge Brain Sciences (CBS) will also record your internet protocol (IP) addresses. Storage of your IP address runs the risk of additional privacy breaches that is associated with your IP address for example your network, device or service. Your IP address also provides information on the following areas, online services for which an individual has registered; personal interests, based on websites visited; and organizational affiliations.

For use of third party reimbursement companies:

You will be reimbursed for expenses related to this study such as <insert all study related expenses, e.g. travel, hotel>. Payments will be administered through <state company name and location>, a company working on behalf of the study sponsor. Please note being reimbursed and/or providing personal information to <state company name> is optional and an alternative of being reimbursed through your study site can be made available to you.

In order to process your reimbursement <state company name> will need to access personal information about you such as, <insert all personal information that is required, e.g. name, address etc.>. You will need to contact the company at <insert contact information> **OR**

the study staff will provide your personal information to <company name>. <Company name> will not share your personal information to anyone including the study sponsor, and will not sell or distribute your information for any purpose outside of this study. The <company name> will retain your identifiable information for <insert number> of years/months, after which it will be destroyed.

If you do not want your personal information to be provided to <state company name>, you can be reimbursed through the study site. You will need to contact <name the individual e.g. the study doctor/study coordinator> about what is required for example, keeping all study related receipts and they will help guide you through this process.

If there is any further information regarding reimbursements this should be entered here. For example, if participants will receive direct reimbursements, or if they will be issued a debit/Visa/MasterCard and any security features, e.g. Canadian vs. American laws.