Western Research

Western University
Room 5150 Support Services Building, 1393 Western Road
London, Ontario, Canada, N6G 1G9
Tel: 519-661-2161
ethics@uwo.ca

Guidance Document	Mandatory Informed Consent Form Template for Clinical Trials
Effective Review	HSREB; Full Board
Version Date	October 01, 2025

Clinical Trial Informed Consent Form Template

Instructions:

This Clinical Trial Informed Consent Form (ICF) Template has been designed to meet current regulatory and ethical standards. The Clinical Trials Ontario (CTO) template has been used as the basis for this document with only minor modifications.

The ICF template uploaded into the Western Research Ethics Manager (WREM) system must follow the prescribed structure and format as set out in this template. This applies to all clinical trials as defined by the World Health Organization. Non-clinical trials should still follow the HSREB Non-Clinical consent guidance. Consent forms will be screened by the Office of Human Research Ethics for concordance with this template. Consents that do not meet these requirements will be sent back to the study team for revision before the study can be reviewed.

The Summary of Informed Consent Form on page 3 of the template should only be included for studies funded or supported by a US federal funding agency. **DO NOT include a Summary for studies not meeting this criterion.

How to use this template:

- Suggested text/examples in **blue font** may be omitted if they are not relevant to the specific protocol, or revised as applicable
- London Hospital Documented Institutional Ethics Requirements in **green font** must only be used for studies with hospital oversight as indicated in Q1.2 of WREM.
- Headings in UPPERCASE, UNDERLINED BLACK FONT denote sections which should not be altered. All text included in the consent form must be applicable/appropriate for that specific clinical study
- Instructions are indicated in *italics/grey background*
- Turquoise highlighting provides a prompt to adapt text to the research study (e.g., to select from the available options highlighted)
- Open Label Extension studies universally require a separate ICF.
- Hospital-affiliated researchers must also consult current Documented Institutional Ethics Requirements (DIERs) for letterhead and other required language to be added.

When writing the consent, please remember to:

- Delete this instructional page
- Use plain (lay) language that is easy for a non-medical person to understand and is consistent with the study population; use clear short words, sentences, and paragraphs; keep language consistent

- Avoid the use of legalistic language (Examples are: “I understand…,” “You understand…,” “authorize” etc.)
- Use a size and font of text that is consistent and easy to read (size 11 or larger is recommended); use appropriate margins; avoid capitalizing full sentences and/or phrases; ensure the headings match the text
- Avoid repetitions and extensive use of abbreviations
- Define all acronyms, abbreviations, and medical terms when they first appear
- Use the term ‘study doctor’ when referring to physicians involved in the clinical study, to ensure there is no confusion with the treating or primary care doctors. Non-physician investigators should be referred to as ‘researchers’ and refer to the study participants as “participants” rather than “subjects”
- Do not refer to a study intervention as “treatment”
- Ensure that the final form is properly formatted and free of spelling or grammar errors
- After all edits have been made, all text should be **black**
- Use terminology accurately, for example:
    - de-identified/coded information – direct identifiers are removed from the information and replaced with a code
    - anonymized information – the information is irrevocably stripped of direct identifiers; a code is not kept allowing future re-linkage
    - anonymous information – the information never had identifiers associated with it

REMINDER:

The informed consent form is only a component of the informed consent process. Researchers still need to have an informed discussion with, and respond to any questions raised by, participants. Consent is an ongoing process throughout the conduct of the study to ensure consent for participation is maintained.

[Institutional Logos as applicable: Western, LHSC, LRI, **NO sponsor or funder logos**]

ONLY for studies funded or supported by a US federal funding agency (e.g., NIH, DHHS, etc.) include this summary of information as required by the US federal regulations. This summary should contain only the information that is most likely to assist a prospective participant in understanding the reason for or against participating in the research, as outlined below. Some items included in the summary section may be repeated in the subsequent consent sections if necessary to ensure the subsequent sections make sense or if the information is core to informed consent (e.g., risk of death), otherwise duplication should be avoided.

Summary of Informed Consent Form

Study Title: *insert study title as written on the protocol*

Below is a summary of information about the study. There is more information in the document called an "informed consent form" that follows this summary. Please read the informed consent form. The research team will also talk to you about the study and you can ask any questions you may have.

Participation in research is voluntary. It is your choice whether you take part in this clinical study.

STUDY PURPOSE

The purpose of this study is *provide a brief description of the primary reason why the research is being conducted, no more than 2-3 sentences.*

DURATION

It is expected that study participation will last *provide expected duration*. Participants will be followed for *define period of time*.

STUDY PROCEDURES

Briefly describe the study design, intervention(s), highlight key study procedures and, if applicable, outline procedures that may be lengthy/burdensome to participants
This study is looking at *describe interventional group(s)*. Participants will also *briefly describe key procedures e.g., study visits every X weeks during which the researchers will do some tests*.
If applicable:
You will be asked to do *describe lengthy or burdensome procedures* which may take *specify time* extra time.

RISKS

Describe the most important risks. Consider those most probable and/or highest magnitude of harm. Key information should not include the full list of risks.
Participation in this study may involve risks to you. These risks are described in detail in the informed consent form.

Include the risks participants are most likely to experience. This should not include the entire 'very likely' or 'likely' category from the main consent. Researchers must review the risks and identify those that are most likely.
The risks you are most likely to experience are:

- *Specify risk in lay language with expected frequency*

If applicable, include any serious risks. For the purposes of this summary, serious risks are considered those that may result in death, is life-threatening, requires hospitalization/prolongation of existing hospitalization, results in permanent disability/incapacity or in a birth defect.

The most serious risks are:

- *Specify risk in lay language with expected frequency*

BENEFITS.

Insert direct benefit, or state if there is no direct benefit. If direct benefit to participant is unknown but there is a greater benefit to society, include for example:

We do not know if you will receive medical benefit from participation, but researchers hope that this study will fulfil its purpose and benefit others in future.

ALTERNATIVES.

You do not have to participate in this study to receive medical care.

If applicable:

You may have other medical options – you should discuss this with your health care provider.

[Institutional Logos as applicable: Western, LHSC, LRI, **NO sponsor or funder logos**]

Informed Consent Form for Participation in a Research Study

Study Title: *insert study title as written on the protocol*

Sponsor's Study ID/Protocol Number: *Insert sponsor's study ID/protocol number if applicable*

Principal Investigator: *insert name, department and telephone or pager number*

Sponsor: *Insert the name, city, and country of the Sponsor (as documented on the protocol and/or application form)*

Funder(s): *Insert the name of the funder, if applicable (a funder is responsible for providing funding for the study only, and is not responsible for the conduct of the study)*

Emergency Contact Number (24 hours / 7 days a week): _____

Non-Emergency contact numbers are noted at the end of this document under the section heading "Contacts".

Please note that the security of e-mail messages is not guaranteed. Messages may be forged, forwarded, kept indefinitely, or seen by others using the Internet. Do not use e-mail to discuss information you think is sensitive. Do not use e-mail in an emergency since e-mail may be delayed.

INTRODUCTION

For studies where consent is sought through a substitute decision maker, include the following paragraph:
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.If the participant gains the capacity to consent for themselves, your consent for them will end. T

You are being invited to participate in a clinical trial (a type of study that involves research). You are invited to participate in this clinical trial because you have *Explain the main features of the population to which the research applies. Do not use an extensive list of inclusion/exclusion criteria.* This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study. If you would like to, you can talk about this clinical trial with other people (for example your family, your friends, , and your usual doctor or health care provider).

If time permits:
Please take your time in making your decision.

Or, for clinical studies where participants must start intervention within a specific timeframe due to best practices for participant population/disease:
The study staff will tell you about the study timelines for making your decision.

[Institutional Logos as applicable: Western, LHSC, LRI, **NO sponsor or funder logos**]

Taking part in this study is voluntary. You do not have to participate at all or you may choose to leave the study at any time. Whatever you choose, it will not affect the usual medical care that you receive outside the study *include if applicable:* however, it may affect your future health care options. This will be discussed with you. If you have any questions about this, you can ask the study team. *Specify any other potential areas where participants might be concerned about a potential penalty or discrimination (e.g., academic standing, employment, etc.)*

IS THERE A 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 including 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 options below.

Option 1:

Members of the research team have a professional interest in completing this study (e.g., academic achievement, presentation of results, etc.). Their interests should not influence your decision to participate in this study.

Option 2:

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 details about this payment. Their interests should not influence your decision to participate in the study.

Option 3:

The *insert recipient of funding, e.g., name of hospital/name of institution* is receiving financial payment from the Sponsor/Funder to cover the cost of conducting this study. Their interest in completing the study should not influence your decision to participate.

Option 4:

Insert name of company, the sponsor of this study, will reimburse the hospital and study doctor/researcher(s) for the costs of doing this study. All of these people have an interest in completing this study. Their interests should not influence your decision to participate.

Option 5:

There are no conflicts of interest to declare related to this study.

If you would like additional information about the funding for this study, or about the role of the doctor in charge of the study, please speak to the study staff or contact the Patient Relations Office [at LHSC at (519) 685-8500 ext. 52036/at St. Joseph's at 519-646-6100 ext. 61234.]

WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?

Describe the background information relevant to the study, including (as applicable) the standard of care for the population, the reason for conducting the clinical trial in lay language, and the nature of the application with Health Canada. Examples are provided below.

Each participating site must ensure that the standard or usual treatment described below matches the standard of care at that site. Site specific differences must be reflected in the Centre Initial Application and the site-specific consent form.

The standard or usual treatment for *specify condition* is *describe the standard treatment* or how there is no standard treatment.

Insert name(s) of product/agent/device is a new type of *describe, e.g., natural health product/drug/device* for *specify condition.* Laboratory tests show that it may *explain laboratory results in lay terminology, e.g., [agent] has been studied in a few people and seems promising, but it is not clear if it can offer better results than standard treatment.*

This study is being conducted to determine whether *insert name(s) of product/agent/device* can *insert reason the study is being conducted, i.e., hypothesized outcome.*

For studies under Health Canada oversight, include one of the following options, as applicable

Option 1: product/agent/device approved by Health Canada, to be used for new (not approved) condition, or to be used outside of the approved dosage/schedule
Health Canada, the regulatory body that oversees the use of natural health products/drugs/devices in Canada, has not approved the sale or use of *insert name(s) of product/agent/device* for *specify change from approved parameters, e.g. this condition.* Health Canada has allowed *insert name(s) of product/agent/device* to be used in this study for these other purposes.

Option 2: product/agent/device not approved by Health Canada
Health Canada, the regulatory body that oversees the use of natural health products/drugs/devices in Canada, has not approved the sale or use of *insert name(s) of product/agent/device*. Health Canada has allowed *insert name(s) of product/agent/device* to be used in this study.

This is the first time *insert name(s) of product/agent/device* will be tested in humans.

WHY IS THIS STUDY BEING DONE?
Explain the purpose of the study in lay terminology

The purpose of this study is *explain the purpose of the study, using suggestions below as applicable.*

Suggestion - Pilot study
The purpose of this study, called a pilot study or a feasibility study, is to test the study plan or 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 the safety or effectiveness of *insert study intervention*. 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 *insert name(s) of product/agent/device*, to see what effects it has on individuals.

Or, for Phase I Studies
The purpose of this study is to find the highest dose of *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. 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 only 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 *insert name(s) of product/agent/device* has on individuals with *specify condition*.

Suggestion - Phase III Studies
The purpose of this study is to compare the effects on individuals with *specify condition* of *insert name(s) of product/agent/device,* compared to other *natural health products/drugs/devices* which are commonly used for *specify condition*.

Or, for Phase III 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*.

Explain why using a placebo is necessary. See suggestions below:

For drug trials
A placebo is given in this study to reduce the chances of believing that a disease is getting better because one is receiving a new drug. We don't know if the new drug or no drug *insert, if applicable, with or without the standard drug* is better than the other so we are doing this study to try and find this out.

Or, more generically
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.*

WHAT OTHER CHOICES ARE THERE?

Explain the alternative options applicable to the study population, and their important potential benefits and risks. Refer to suggestions below as applicable.

Suggestion for therapeutic intervention studies
You do not have to take part in this study to receive treatment or care. Other options (in addition to the standard or usual treatment described above) may include, but are not limited to:
List options available to participants (examples below may be used as applicable). The standard of care does not need to be repeated in this list.

- No therapy at this time
- Palliative care or Best Supportive Care (BSC). This type of care helps reduce pain, tiredness, appetite problems and other problems. It does not treat your condition directly but instead tries to

improve how you feel. BSC tries to keep you as active and comfortable as possible.
- Other research studies may be available if you do not take part in this study
- Usual care as described above

Please talk to your usual doctor or the study doctor about the known benefits and risks of these other options before you decide to take part in this study. Your usual doctor or the study doctor can also discuss with you what will happen if you decide not to undertake any treatment at this time.

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

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that *insert potential number of participants* people will take part in this study, from research sites located in *indicate participating countries*.

This study should take *total length of study in months or years* to complete and the results should be known in about *time to anticipated analysis in months or years*.

WHAT IS THE STUDY INTERVENTION?
Describe intervention by study group, including a clear identification of experimental components of the study. See suggestions below. If these suggestions are not applicable, provide a detailed description appropriate to the specific protocol.

Suggestion for single arm studies
Experimental Intervention:
If you agree to take part in this study, you will *identify intervention, including description of method: e.g., receive [agent] by needle into one of your veins; you will take [agent] pills by mouth; you will complete X procedure, etc. Include length of procedure/intervention for all non-oral interventions e.g., the procedure will take about <X> minutes. Include frequency of intervention for multiple study visits e.g., this will happen every <X> weeks for <X> months.*

Suggestion for multi-group studies. Ensure that the Group/Arm names and descriptions are consistent with the protocol.
Group 1 (Experimental intervention): Standard intervention *(specify drug name/regimen/ intervention)* plus experimental intervention *(specify drug name/regimen/intervention)*

If you are randomized to this group you will *identify intervention, including description of method: e.g., receive [agent] by needle into one of your veins; you will take [agent] pills by mouth; you will complete X procedure, etc. Include length of procedure/intervention for all non-oral interventions e.g., the procedure will take about <X> minutes. Include frequency of intervention for multiple study visits e.g., this will happen every <X> weeks for <X> months.*

Group 2 (Non-Experimental Intervention): Standard intervention *(specify drug name/regimen /intervention)*

If you are randomized to this group you will *identify intervention, including description of method: e.g., receive [agent] by needle into one of your veins; you will take [agent] pills by mouth; you will complete X procedure, etc. Include length of procedure/intervention for all non-oral interventions e.g., the procedure will take about <X> minutes. Include frequency of intervention for multiple study visits e.g., this will*

happen every <X> weeks for <X> months.

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 studies

If you decide to participate then you will be "randomized" into one of the groups. 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., an equal/one in three* chance of being placed in either/any group. No one 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 and the study team will know which group you are in.

Or, for single-blind studies

You will not know which group you are in, but the study team will.

You will be told what group you were in once your study participation is complete and all data has been collected from you.

Or, for double-blind studies

This is a double-blind study, which means that neither you or the researcher will know which group you are in. Your group assignment can be identified if medically necessary, but otherwise you will not be told what group you are in until the entire study has been completed and the results are published. Requests to reveal your assignment for your own information will not be considered until the entire study has been completed and the results are known.

If applicable, include the following:

However, this information could be revealed if needed for your safety to participate in other research studies or another study team requests such as information to determine your eligibility for that study.

Example for clinical studies with intervention assigned based on protocol-specific criteria

If you decide to participate then you will be assigned into one of the groups. 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.

WHAT ELSE DO I NEED TO KNOW ABOUT THE STUDY INTERVENTION?

Include the relevant information from the selection below

If you have side effects while you are on this study, the study doctor may make changes to the intervention.

If participation in the study restricts future treatment options, inform participants of details. See suggested text or revise as applicable.
If you are in *identify restriction, e.g., this study; Group 1*, you may not be able to receive *identify any future treatment options that participant would be excluded from* in the future.

If standard treatment is being withheld or withdrawn, inform participants of details. See suggested text or revise as applicable.
Normally, you would receive *identify standard treatment* for *specify condition*. If you decide to take part in this study, you will/may not receive this usual treatment.

For studies with washout period, provide details on washout requirements. See suggested text or revise as applicable
As part of this study, you will be asked to stop taking *identify washout agent* for a period of *insert washout period in weeks/months* before you begin the study intervention.

If applicable, include if participants who are benefiting from the experimental intervention will NOT continue to receive the intervention after the study is finished. Wording may be altered according to the type of study or drug, or omitted in the case of adjuvant clinical studies
You may not be able to receive the study intervention after your participation in the study is completed. There are several possible reasons for this, some of which are:

- The intervention may not turn out to be effective or safe.
- The intervention may not be approved for use in Canada.
- Your caregivers may not feel it is the best option for you. The study doctor will talk to you about your options.
- You may decide it is too expensive and insurance coverage may not be available.

Include if participants who are benefiting from the experimental intervention will continue to receive the intervention after the study is finished. Wording may be altered according to the type of study or drug, or omitted in the case of adjuvant clinical studies.
After the study is completed, if the study doctor feels that you are benefiting from the experimental intervention, you will continue to be provided with *insert name(s) of product/agent/device*.

WHAT ARE THE STUDY PROCEDURES?

Describe the procedures that are used in the study, including clear identification of those procedures that are study specific. The consent should focus on these procedures and discuss the standard of care only where necessary. Each procedure/intervention should be described only once.

If participants' medical records must be accessed for the purposes of the study, outline specific information that will be retrieved from participants' medical records.

Study-Related Procedures

The following tests will be done as part of this study. Some of these tests may be done as part of your standard care, in which case the results may be used. Some of these tests may be done more frequently than if you were not taking part in this study and some may be done only for the purpose of the study. If the results show that you are not able to continue participating, the study doctor(s) will let you know.
List the procedures and tests. Include a lay explanation of what each test involves.

-

If there are experimental procedures or medical tests, include the following section. Any standard procedures (e.g., MRI, blood draw, etc.) that are outside of standard of care should be included in the 'non-experimental procedures' section – this section is for procedures that are experimental (e.g., being tested as part of the research):

Study-Specific Procedures
Explain any risks of study-specific procedures and medical tests in the risk section

The following test(s) is/are considered study specific 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 at *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.

Interviews

You will be asked to participate in *specify how many* interviews *if more than one, provide information about timing e.g., before you begin the study and then every X weeks/months*. During this interview, you will speak with/meet with a member/members of the research team and *specify others if applicable.* Each interview will be about *specify length in minutes or hours* in length and will take place *specify location*. You will be asked to provide information about *explain topics of discussion e.g., your experiences with condition/intervention*.

If audio/video records used:
You will be audio/video recorded during the *specify e.g., interview(s)/focus group*.

If questionnaires are administered during the study, 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 they should 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:
Responses *[will/will not]* not be reviewed by your health care team or study team. [*if 'will not' also add*, 'If you wish them to know this information please bring it to their attention'].
The HSREB suggests measures indicating suicidality be reviewed within 24 hours by local study team with a plan for the PI to act be outlined in the ethics application

If participant diaries are to be completed during the study, 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 participating site.

If central review is a required 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 diagnostic imaging 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* when then they will be destroyed.

To protect your identity, the information that will be on your *specify material, e.g. scans/specimens* will be limited to *specify which identifiers will be on the review material(s)*.
If additional personal information is also being provided to the central review location (e.g., on additional forms provided with the review materials), include a description of the information provided.

If the research includes mandatory health information collection from a database or medical record, include this section
COLLECTING HEALTH INFORMATION FROM A DATABASE OR MEDICAL RECORD FOR RESEARCH USE

If health information will be collected from the participant's medical record:
If you agree to participate in this study, the study team will collect the following health information from your *insert institution name* medical record:
List the categories or types of health information that will be collected from the medical record and the approximate time frame of the data that will be collected (examples below may be used as applicable):

- *All past diagnoses and treatments*
- *Medication history from the last 5 years*
- *Test results from procedures done as part of your routine care*

If the research includes mandatory specimen collection, include this section

MANDATORY SAMPLE COLLECTION

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

Quantify the amount of body fluids/tissue to be taken at each visit. If quantifying in spoons, indicate in mL as well.
Indicate number of visits and indicate, as applicable, if any hospitalizations are required and if procedures are to be performed outside of the main research site.

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. 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.

Describe who will be informed of the results of the mandatory research. For example:
Results from any research tests done with your samples will not be given to you, your doctor, or other health care provider(s). These reports will not be put in your medical records.

Or:
Results from 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. *Specify whether results will be placed in the individual's medical record.*

Tissue Collection

Describe the method of tissue sample collection and associated risks. Specify the location (city and country only) 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 archived specimens are required from another institution, include the following:
If your biopsy or surgery were completed at another institution, signing this consent form means that you are consenting to the collection of your tissue sample, together with any related personal health information, from that institution.

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 an overnight hospital stay may be required.*

Identify location where specimens will be retained. For example:
These tissue samples will be sent to a laboratory at *insert location (city and country only)* where they will be examined.

Or:
Tissue samples shall be provided to the following locations for analysis:

- *Insert location(s)*

Blood/Bodily Fluids Collection
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.

Blood samples will be taken by inserting a needle into a vein in your [*body part*]. 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 *insert location (city and country only)* where they will be examined.

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 *insert location (city and country only)* where they will be examined.

If applicable:
Reportable Disease Testing
This study involves testing to determine if you have *insert name(s) of reportable diseases, e.g., HIV, Hepatitis B/C, etc.* Positive test results will be reported to local health authorities, Public Health. If you have concerns about being tested for *insert name(s) of reportable diseases, e.g., HIV, Hepatitis B/C, etc.* and the consequences of testing positive, please speak to your study doctor or your usual doctor before providing your consent to be tested.

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…

If the study includes genetic testing, include the following:
Genetic Testing
Genetic risk increases with the scope of the genetic intervention. With greater application of whole genome/exome sequencing, you should consider the likelihood that inheritable conditions or actionable genetic incidental findings may be discovered during the course of the research. This risk should be reflected in the consenting process. In general, these risks are not applicable to pharmacogenetic testing of specific drugs or drug combinations.

The below provided examples are applicable to genetic testing, including whole genome/exome sequencing, aside from pharmacogenetics or pharmacogenomics.

This study involves genetic testing. Genetic testing examines your DNA, the material that carries the instructions for your body's growth, development and function. DNA is made up of individual units called genes that determine things like eye colour, height and your risk for certain health conditions. Researchers will be looking at your genes (DNA).

Include the following if the study has genetic information or collection of samples

Research with genes involves studying changes that are passed on in families. Studying DNA can help explain why some people respond to some medications and others do not as well as why some people develop certain diseases and others do not. If you agree to genetic testing, researchers may study your sample, examine your DNA and compare it with the information already collected about you

Include if applicable (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen):
This study will involve whole genome sequencing. Whole genome sequencing is the analysis of the complete set of genetic instructions in a cell and is considered personally identifying information.

Your whole genome sequence data will be stored at *insert location (city and country only)* for *insert retention period*.

You will be given the choice/not be given the choice to find out about genetic testing results.

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.

Summary of Tests and Procedures

When the study involves a number of visits, e.g. more than 2-4, then provide a table with a summary of procedures, including the approximate time commitment (as applicable, based on the protocol).

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?
Identify participant responsibilities. Include, add to, or modify bullets below as applicable.

If you choose to participate in this study, you will be expected to:

- Tell the study doctor about your current medical conditions.
- Tell the study doctor about all prescription and non-prescription medications and supplements, including vitamins and herbals, and check with the study doctor before starting, stopping or changing any of these. This is for your safety as these may interact with the intervention you receive on this study.
- Tell the study doctor if you are thinking about participating in another research study.
- Return any unused study medication.
- Return any *specify e.g., diaries or questionnaires* that you take home to complete.
- Tell the study doctor if you become pregnant or get someone pregnant while participating on this study.
- Avoid drinking/eating *specify what and for how long*
- Stop taking *name* for *specify washout period*

- *insert name of study intervention* is for you alone and must not be shared with others. *If applicable, include:* If someone accidentally takes *insert name of study intervention*, *include instructions, e.g., they should immediately go to the nearest emergency department.*
- Do not discuss with others any information you learn in the focus group. This includes information about other group members and any opinions or comments that are shared.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

You may experience side effects from participating in this study. Some side effects are known and are listed below, but there may be other side effects that are not expected. You should discuss these with the study doctor.

The study doctor will watch you closely to see if you have side effects. When possible, other medicine will be given to you to make side effects less serious and more tolerable. Many side effects go away shortly after the study intervention is stopped, but in some cases side effects can be serious, long-lasting, permanent, or may even cause death.

For studies using non-marketed drugs or other investigational interventions, if applicable
If you experience serious side effects that require treatment between regular clinic/hospital visits, it is important that you make every effort to return to the clinic/hospital where *insert name of product/agent/device* was given. Because *insert name of product/agent/device* is experimental and is only used in clinics/hospitals involved in research studies, any serious side effects may be best treated by these clinics/hospitals. If you experience a serious side effect and need immediate treatment and are unable to return to the clinic/hospital, please call 911 or go to the nearest emergency room. Then the study doctor should be contacted as soon as possible.

Risks and side effects related to the experimental intervention *insert name of product/agent/device* we are studying include:

- ✓ ***Nature of risks to include:*** *Describe all reasonably foreseeable risks, harms, or discomforts. Include both physical and psychological/emotional risks as applicable to the research; Reminder: A rare but serious finding from previous studies (e.g., death, severe pneumonitis, acute renal failure) should be placed at the top of this list;*
- ✓ ***Language:*** *Include lay language explanation of any side effects;*
- ✓ ***Categorization:*** *When detailed information about the side effect profile for the intervention is known, categorize risks by frequency. Examples of these categories are provided below - other categorizations may be used depending on the presentation of risks in the Investigator Brochure/Product Monograph;*
- ✓ ***Information to provide****: Frequency, severity, and long term impact or reversibility. When applicable, specific symptoms for serious side effects of which the participant should be aware (e.g., in order to seek immediate medical assistance) should be included*
- ✓ *Include risk of receiving placebo/delayed surgery/delayed/withdrawn standard of care treatment, if applicable*

Example categories (adjust associated probability calculations on a per study basis). This information may also be presented in list or table format:
Very likely (51% – 100%) In 100 people receiving study drug, between 51 and 100 may have:

-

Likely (21% – 50%): In 100 people receiving study drug, between 21 and 50 may have:

-

Unlikely (5% – 20%): In 100 people receiving study drug, between 5 and 20 may have:

-

Rarely (1% – 4%): In 100 people receiving study drug, between 1 and 4 may have:

-

When limited numbers of individuals have been exposed to the intervention and the risks cannot accurately be quantified, the following language should be included (if applicable):
As of *insert date*, *specify number* people have been given this intervention and the side effects that have been reported are:

- *Specify number* experienced *specify side effects, e.g., headaches*

It is not yet known if these side effects are caused by the study intervention or how likely these side effects will be.

Or, if applicable:
Insert name of product/agent/device 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 using lay language*.

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

If a comparison arm includes standard of care treatment/intervention along:
The risks and side effects of the standard or usual treatment will be explained to you as part of your standard care. These risks are not included in this consent form.

It is possible that other drugs (prescription and non-prescription drugs), vitamins, or herbals can interact with the study intervention. This can result in either the intervention not working as expected or result in severe side effects. Please check with the study team if the study drug may interfere with your medications and consult with the study team before taking any new medications.

If standard treatment is being withheld or withdrawn, inform participants of any risks associated with this. See suggested text or revise as applicable:

Normally, you would receive *identify standard treatment* for *specify condition*. If you decide to take part in this study, you will/may not receive this usual treatment. This may cause some potential risks:

- Specify risk(s) in lay language, e.g., withdrawal symptoms, return of symptoms for condition, etc.

If you experience any of these symptoms/effects, please contact your study doctor *or add any specific recommendations to manage these effects*.

If participation in this study puts the participants at increased risk of long-term effects such as cancer, include the following

Long term effects of the *specify test/intervention* used in this study include an increased risk of developing *specify long-term risk, e.g., cancer*.

Should an experimental combination of the drugs be administered during the study, then potential side effects should be listed for each of the drugs individually. Then, under the combination, only side effects not listed for either of the drugs and/or side effects that have been seen at the increased frequency with either of the drugs administered alone should be presented.

Possible treatment options of side effects should not be discussed in the consent form as, should a side effect occur, it would be treated according to the individual's situation and might differ from the options listed in the consent form. Moreover, it may leave impression that treatment options of side effects are part of the study intervention, while they are not.

Risks of Study-Related Procedures:
It is not necessary to describe the risks associated with tests or procedures with which the participant population would already be familiar.

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

If there is a possibility that a medically relevant sample will be exhausted:
Archived Tumour Tissue Collection
There are no physical risks to you in releasing archived tumor samples for the purpose of this study since the tissue has already been obtained by a previous biopsy/surgical procedure. However, it is possible that, if your tissue is released for this study, there will not be enough of your tissue sample left for any possible future testing that may need to be done in the future. Please speak to the study doctor to discuss this possibility.

Genetic Testing
Every person has their own unique set of genes or 'genome'. The reason this is important is because these results might contain information (for example, an inherited genetic disease) that could impact you or your biological (blood) relatives. When you donate your genetic information or materials you are sharing information about yourself, and it can be used to identify these relatives.

Even with protections in place, absolute confidentiality cannot be guaranteed that your information could be released by accident. Advances in technology could also increase the risk that your genetic samples and results could be linked back to you or your relatives. There is no way to predict what effects such an information loss would have. For example, if an insurer, a current or future employer, or law enforcement were to learn your genetic code it could result in loss of privacy and to possible future discrimination in employment or insurance against you or your relatives. Even though this risk is unlikely, we think you should be aware.

Focus Group/Interview
There are no medical risks to you from participating in this study procedure, but taking part in it may make you feel uncomfortable. You may refuse to answer questions or leave the group/interview at any time if you experience any discomfort.

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.

Data Transfers
This study requires the transfer of identifiable information to *insert name of institution/individual* for the purposes of *specify purpose*. The following information will be transferred:

- *Specify identifiable information to be transferred*

The risk is small, but a person might be able to tell which information is ours even if we remove your name or other identifiers. This risk could be higher in the future as people invents new technology. We try to prevent this by having contracts with the organizations we give information to.

Other Concerns
Depending on study design and study population there might be other concerns/risks, e.g. risks from radiation dose, risk to fertility etc., that vary from individual to individual and, thus, are not reflected above.
If you have any questions or concerns about risks from *insert study intervention, e.g. the radiation dose you may receive from study procedures*; whether your fertility (ability to have children) could be affected by the *insert study intervention;* whether your future treatment options could be affected by the *insert study intervention,* please discuss these questions and concerns with your study doctor.

WHAT ARE THE REPRODUCTIVE RISKS?
If the agent(s) used in the study presents a real or potential risk of fetal or reproductive harm, this must be described. Generic wording for unknown risk is included below. If the study includes participants of a single gender, ensure this is reflected in the consent form.

If there are risks related to being or becoming pregnant or getting someone pregnant:
The effects that *insert name of product/agent/device* may have on eggs (ova), sperm, or on an unborn baby (fetus) are unknown/*[detail the known risks]*. You should not become pregnant or get someone pregnant during the study and for *identify post-intervention period as applicable* after the last dose. You must use an appropriate family planning method as discussed and decided upon in consultation with a study doctor.

If you become pregnant or get someone pregnant while taking *insert name of product/agent/device* or for *insert length of time afterward*, you should immediately notify the study doctor, who will discuss next steps with you.

If there are risks related to being or becoming pregnant:
If you are able to become pregnant, a study doctor will order a blood/urine pregnancy test prior to the start of your participation in this study to confirm that you are not pregnant. To confirm that you have not become pregnant during the study, blood/urine pregnancy tests will be done throughout your participation in the study.

(This language is compliant with SJHC DIERs)
If the participant will be asked to consent to allow the study team to follow a pregnancy that occurs during this study:
If you become pregnant or get someone pregnant while you are taking the study drug, the study team may ask if you/the person who is pregnant would be willing to provide information about the pregnancy as part of this study. A separate consent document will be used to request permission to collect this information. You/The person who is pregnant may choose not to give consent for the collection of this information or may withdraw consent at any time without giving a reason. This decision will not affect your participation in this study and will not affect the health care that any person receives.

If there are risks to a nursing infant:
You should not nurse (breastfeed) an infant while in this study because *insert name of product/agent/device* may be present in your milk and could be harmful to a nursing infant.

If there are risks to future reproductive ability:
Insert name of product/agent/device used in this study may affect your ability to reproduce (become pregnant or produce sperm) in the future. A study doctor will discuss this with you.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?
Inform participants of potential benefits to themselves and in general that may arise. If there is no known clinical benefit, ensure this is stated.

If there is no likely medical benefit to participation (e.g., phase I study), include the following
There are no medical benefits to you for taking part in this study.

If the benefit is known, include
The expected benefit from taking part in this study is *specify*.

If the potential benefit is unknown, include
If you agree to take part in this study, the experimental intervention may or may not be of direct benefit to you.

For placebo-controlled studies, include the following
You will not benefit from the placebo used in this study.

If applicable, include
We hope the information learned from this study will help other people with *specify condition* in the future.

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?
Specify the duration of intervention, follow-up schedule, and total length of research involvement. See suggestions below, or revise as applicable to the research

The study intervention will last for about *insert duration. If intervention length varies by group assignment, ensure this is specified.*

Briefly describe follow-up visit schedule, as applicable. Suggested text is as follows:
You will be asked to come back to the *specify location, e.g., clinic/hospital* at *specify time period, e.g., 30 days after the last dose of study intervention*. You will then be asked to come back *describe follow-up schedule, e.g., every X months for X years*.

You may be seen more often if the study doctor determines that this is necessary.

If there is long-term follow-up as part of the study, include the following as applicable
No matter which group you are randomized to, and even if you stop the study intervention early, we would like to keep track of your health for *define period of time* to *describe purpose of long-term follow-up, e.g., look at the long-term effects of your participation on this study*. We would do this by *specify follow-up method and frequency, e.g. having you come back to the hospital/clinic [or] having someone from this centre call you to see how you are doing*.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. If you choose to withdraw from the study, you are encouraged to contact the study doctor or study staff.

If a participant who withdraws will be asked to come in for an end of study visit or to be followed for safety purposes:
You may be asked questions about your experience with the study intervention, and to have laboratory tests and physical examinations considered necessary to safely stop your study involvement. *Describe any end-of-study research activities that are mandatory for participant safety and outline any safety assessments that are recommended if the participant withdraws from this study early, e.g., at the time of your withdrawal, you will be asked to participate in [insert recommended assessments].*

If a participant can withdraw from the intervention and still participate in follow-up activities:
During the study, you can decide to withdraw from the intervention portion of this study but continue to participate in follow-up data collection activities and/or study visits. *Describe the steps that will be required to withdraw from the intervention portion of the study. List the study activities and procedures they could still take part in without continuing with the intervention.*

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.

- *If the study site continues using the participants' data after they have withdrawn from the study, it must be justified to the REB and explained to the participants; Canadian Guidelines (TCPS) state that participants should be able to request that data and sample(s) be withdrawn unless withdrawal of data or samples may not be possible or is impracticable.*

Describe the process for withdrawal of samples. See the suggested text below, or revise as applicable:
If you decide to leave the study or no longer want your samples to be used in this research, you have the right to request withdrawal of *insert types of samples as applicable to study, e.g., blood, tissue, etc.* Let your study doctor know 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 and 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 anonymized. "Anonymized" means the link between your personal identifying information and study ID/data will be deleted. After records linking your identity to your sample(s) are destroyed, 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

For clinical studies with regulatory oversight, include the following:
If you leave the study, information that was recorded before you withdrew will be used by the researchers, but no information will be collected without your permission after you withdraw from the study.

Or, if the participant can withdraw information collected prior to withdrawal
If you decide to leave the study, you can ask that the information that was collected about you not be used for the study. Let the study doctor know if you choose this. Some records of your participation in this study will/must be retained, for example this signed consent form.

If this study involves sub-studies or optional research activities:
Describe whether and how withdrawal from the main study will affect their participation in the sub-study (and vice-versa).

CAN PARTICIPATION IN THIS STUDY END EARLY?

The study doctor may stop your participation in the study early, and without your consent, for reasons such as:
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.
- Staying in the study may be harmful to you (for example, if you experience serious side effects).
- You are unable to complete all required study procedures.
- New information shows that the study intervention is no longer in your best interest.
- The Sponsor decides to stop the study.
- The Regulatory Authority/ies (for example, Health Canada) or Research Ethics Board (REB) withdraw permission for this study to continue.
- 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.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?
Note: *Should there be disclosure of personal identifiers, e.g., disclosed on any research-related information/documents including samples or scans, or as part of the unique identifier, these disclosures must be justified in the REB application and approved. Please ensure that you are aware of institutional and REB policies with respect to the disclosure of personal identifiers.*

If you decide to participate in this study, the study doctors and study staff will only collect the information they need for this study. This may include looking at information obtained from your records already located at this site or getting copies of your records from your health care providers with your permission.

Your data will be shared as described in this consent form and/or as required by law and/or applicable research regulations. Records identifying you at this centre will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed, except as described in this consent document.

Authorized representatives of the following organizations may come to the participating site or be given remote access to an electronic portal (via Internet) to look at your original (identifiable) medical/clinical study records at the centre where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines. These records do identify you, but everyone involved is responsible for making sure that your privacy, and the confidentiality and security of your records is maintained.

Include only those organizations requiring permission for direct access to participant medical records containing identifying information (e.g., permission to conduct on-site monitoring/auditing). Include a brief description of their role in the research. See suggestions below, or modify as applicable to the research:

- *Insert sponsor name, the Sponsor of this study*
- Western University and its Health Sciences Research Ethics Board that oversees the ethical conduct of this study
- The Quality Assurance and Education Officers from the Hospital's Office of Research Services may audit this research study for quality assurance purposes
- Health Canada (because they oversee the use of natural health products/drugs/devices in Canada) *include for studies under Health Canada oversight only*
- Other regulatory bodies (groups of people who oversee research studies outside of Canada), such as U.S. Food and Drug Administration (because they oversee the use of natural health products/drugs/devices in the United States) *include only if applicable (e.g., for studies to US FDA oversight)*

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. The records received by these organizations may contain other information that may indirectly identify you. *(e.g., participant code, initials, sex and date of birth)*

The following organizations may also receive study data:
Include organizations with permission to receive study data only (organizations with direct access must be included in the list above). Include a brief description of their role in the research.

- *List other regulatory authorities* (because they oversee the use of natural health products/drugs/devices in other countries)
- *Identify any other organizations with permission to receive study data only. Include any apps, websites or other partners who will receive data under this study.*

If race/ethnicity information is collected as part of the study, identify this and provide a rationale. See suggested text, or modify as applicable
Studies involving humans sometimes collect information on race and ethnicity as well as other characteristics of individuals because these characteristics may influence how people respond to different interventions. Providing information on your race or ethnic origin is voluntary/required.

For studies using smartphones, apps or applicable 3rd party technology to collect or transfer this study data BEYOND institutional drives/MS 365, specify the data to be collected and describe the security of the device/application, e.g. whether a third party is involved (if yes, for how long and for what purposes – what identifiers will be collected), provide a link to each 3rd party's privacy policy, include country of

data storage, and identify risks etc. For example:

Data [*including name/DOB etc., or, simply De-identified data*] collected using the *insert app/tool/device name* for [*purpose*] resides on the *insert name, e.g., Apple* servers in [*country*] and no assurance can be made about its confidentiality or that it will only be used for research purposes. [*App/tool/device name*] has a privacy policy that can be found here: [*insert URL*].

If an autopsy report is being provided to the sponsor, include the following:
This study does not require that an autopsy be performed. However, if an autopsy is performed for other reasons, and a copy of the report is provided to the study doctor, this report will be sent to the study sponsor as part of the study data collected for this study. This report may contain other health information that is not required for study purposes.

The results of this study may be published, shared or presented at scientific meetings. This information may also be used as part of a submission to regulatory authorities around the world to support the approval of the study intervention. The results and regulatory submissions will not identify you personally – your identity will remain confidential.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

If it is a regulated study, insert the following:
Once the study is complete, the study doctor will keep any personal health information about you and your study records in a secure and confidential location for *insert 7 years for Western-affiliated studies, 15 years for Health Canada, or 15 years for London hospital-affiliated studies/insert 25 years for European Medicines Agency (EMA)* as required.

Or, if it is NOT a regulated study, insert the following:
Once the study is complete, the study doctor will keep any personal health information about you and your study records in a secure and confidential location for *specify* years.

Your participation in this study may be recorded in your medical record at this hospital. This is for clinical safety purposes.

A copy of the consent form that you sign to enter the study may be included in your health record/hospital chart.

If data or samples are to be sent outside of Canada:
Any information and/or samples, sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries dealing with protection of information may not be as strict as in Canada. However, all study data and/or samples, that are transferred outside of Canada will be coded (this means it will not contain your personal identifying information such as your name, address, medical health number or contact information). Any information will be transferred in compliance with all relevant Canadian privacy laws.

Include for US FDA-regulated studies (as per 21 CFR 312.68 and 21 CFR 812.145
Because this study also falls under U.S. regulations, in the event of an investigation of the study, the US Food and Drug Administration (US FDA) may need to copy and take away records that contain your personal information. The FDA may copy records that include your identifying information (like your name) in specific circumstances. The FDA will treat this information confidentially, but they may be

required to share their records (including identifying information), if required by a court of law. You should be aware that privacy protections may differ in other countries.

WILL FAMILY DOCTORS/HEALTH CARE PROVIDERS KNOW WHO IS PARTICIPATING IN THIS STUDY?

Option 1 (required for FDA/HC regulated trials):
The study doctor strongly recommends that your primary healthcare provider (e.g. family doctor) be informed about your participation in this research. With your permission, your provider will be informed that you are taking part in a study for your safety and so that you can be provided with appropriate medical care. If you do not want your family doctor/health care provider to be informed, please discuss this with the study team. A location to indicate your consent is provided at the end of this letter.

Option 2 (may be appropriate for low-risk trials):
Your family doctor/health care provider will not be informed by the study team that you are taking part in the study. You can choose to let your family doctor/health care provider know, if you like.

WILL INFORMATION ABOUT THIS STUDY BE AVAILABLE?

For US FDA-regulated studies (Do NOT modify text)
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.

WHAT IS THE COST TO PARTICIPANTS?
Inform the participant of any anticipated expenses associated with participation in the clinical study

Include if the intervention is supplied for free
The *insert name(s) of product/agent/device/intervention* will be supplied at no charge while you take part in this study.

If applicable:
It is possible that the *insert name(s) of product/agent/device/intervention* may not continue to be supplied while you are on the study. Although not likely, if this occurs, your study doctor will talk to you about your options.

If applicable:
The costs of your medical treatment will be paid for by your provincial medical plan to the extent that such coverage is available.

If participation could result in additional costs, justify such costs to the REB and include an explanation of these potential costs. Ensure that examples of extra costs are consistent with the research project:
Taking part in this study may result in added costs to you. For example:

- *Insert name(s) of product/agent/device/intervention* used in this study may not be covered by provincial insurance. You can speak with the study team about added costs. Everything possible will be done to help you access reimbursement from your insurance company or other third-party payer.
- There may be extra costs that are not covered by your medical plan. Examples of these extra costs could be medications or treatments (such as physiotherapy) to treat side effects that you may experience. If you have private health care insurance, the insurer may not pay for these added

costs.
- There may be costs associated with hospital visits. For example, parking or transportation, or snacks/meals during your stay.
- You may miss work as a result of participation in this study.

Or, if participation will not result in any costs, include the following:

Participation in this study will not involve any additional costs to you or your private health care insurance.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

Describe compensation provided to participants, or state if no compensation is provided. Suggestions are provided below.

If there is no payment for participation

You will not be paid for taking part in this study.

Or, if participants are paid (revise as applicable to the study)

If you decide to participate in this study, you will receive $*specify amount of payment* and type of payment (ex: cash, cheque, gift card, vendor) *including indication of payment interval/payment per task if applicable, e.g., every three months*.

If you decide to leave the study, you will receive payment that is less than the full amount for participating in the study.

If there is re-imbursement of costs for participation

If you decide to participate in this study, you will be reimbursed $*enter actual or maximum dollar amount* for some study related expenses such as *list reimbursable expenses as applicable*.

If receipts or other documentation is required for re-imbursement, this must be justified to the REB and must be described. For example:

You will need to provide your receipts for *insert expense types e.g., parking* to the research staff in order to be reimbursed.

If there is a third party for reimbursements, please explain that a separate optional consent will be provided.

COMMERCIALIZAION

If applicable (alter as needed to fit the research):

It is possible that the research conducted using your study data and/or samples may eventually lead to the development of new diagnostic tests, new drugs or devices, or other commercial products.

If participants will not share in commercial profit:

There are no plans to provide payment to you if this happens.

Or, if participants will share in commercial profits:

If this happens, you will receive *describe participant's share in commercial profit*.

If you are proposing Broad Consent for the future use of data:

The future use of data for secondary purposes (for a new purpose beyond the specific objectives of the original project) requires:

a) separate REB oversight or exemption at the time of the future research and
b) broad consent.
This is distinct from open-access data sharing. Broad consent is defined as consent for future unspecified research. Unlike blanket consent, which is typically unrestricted, broad consent always includes specific restrictions (e.g., consent may be restricted to a particular field of study, to a specific disease, or may prevent use by private industry). Broad consent applies to the storage and secondary use of participants' data and/or human biological materials collected for research purposes. The use of broad consent is in the context of future research being conducted using data and/or human biological materials with no direct contact, consent, or intervention with the participants who provided the data and/or biological materials at that time. While blanket consent is not permitted under the TCPS, broad consent is permitted. Broad consent MUST be optional and contain all information outlined in TCPS2 Article 3.13 (see interpretation https://ethics.gc.ca/eng/policy-politique_interpretations_consent-consentement.html).
Optional Broad Consent for Future Secondary Use of Data

We wish to use your [de-identified, identifiable, anonymous, anonymized] data [and/or biological specimens] for future research related to [scope]. While such research is not planned at this time, it is possible that we may use [and/or share your data with other researchers {at this institution/in Canada/around the world}] in the future. Once data is shared, it cannot be withdrawn [or if it can be, the mechanism to do so]. [If data will be entered into a formal repository, please describe oversight and governance]. It is unknown at this time what the risks of any future research are [if there are known risks such as to genetic research, please state the risks. Any risk of re-identification or incidental findings and how they will be managed need to be disclosed]. You may not personally benefit, but the future research will contribute to knowledge about [scope]. Participation is optional and it will not impact your participation in the current study. A location to indicate your decision is provided on the last page of this document. You [will/will not/may choose to be] be contacted about this future research [*matching option for future contact should be provided on signature page of LOI*].

For Example:
We wish to use your de-identified data for future research related to stress and heart development in children. While this research is not planned at this time, it is possible that we may share your data with researchers around the world. Once data is shared, it cannot be withdrawn. It is unknown at this time what the risks of any future research are, and your data may be combined with other data that may re-identify you to other researchers. You will not personally benefit but the research will contribute to knowledge about heart development. Participation is optional and it will not impact your participation in the current study. A location to indicate your decision is provided on the last page of this document. You will not be contacted about this future research.

WHAT WILL HAPPEN IF THE PARTICIPANT IS INJURED DURING THE STUDY?

In the case of research-related side effects or injury, medical care will be provided by *specify response, e.g., your doctor or you will be referred for appropriate medical care*.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study. Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form you do not give up any of your legal rights against the study doctor, *sponsor* or involved institutions for compensation, nor does this form relieve the study doctor, *sponsor* or their agents of their legal and professional responsibilities.

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

WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT A RESEARCH PARTICIPANT?

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, as applicable. Examples:

If any new information relevant to you *if applicable, include "or your relatives"* 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.

Or

If any new clinically important information about your health is obtained as a result of your participation in this study, you will be informed.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you are experiencing a side effect or have a research related injury, please contact the study doctor or 24h contact number listed on the first page. If it is an emergency, please proceed to your nearest emergency room.

If you have questions about the study or would like to get in touch with the research team, you can contact:

_____	_____
Name	Telephone

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 (OHRE) at Western University (519) 661-3036, 1-844-720-9816, email: ethics@uwo.ca. The OHRE is not part of the study team. Everything that you discuss will be kept confidential.

OR – contact as per institutional DIERs at LHSCRI and/OR LRI as APPLICABLE

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.

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.

[Institutional Logos as applicable: Western, LHSC, LRI, **NO sponsor or funder logos**]

SIGNATURES

Study Title: *insert study title as written on the protocol*

Principal Investigator: insert PI name

CONSENT

- All of my questions have been answered,
- I have read (or someone has read to me) all pages of the information within this informed consent form, including risks, benefits, alternatives to participation and my rights as a participant
- I allow access to my medical records and transfer of specimens and related personal health information as explained in this consent form,
- I do not give up any legal rights by signing this consent form,
- I recognize that my family doctor/health care provider [will/may] be informed of study participation
- I agree, or agree to allow the person I am responsible for, to take part in this study
- I will be given a signed and dated copy of this consent form

_____	_____	_____
Signature of Participant/ Substitute Decision-Maker	PRINTED NAME of SDM	Date

If consent is provided by Substitute Decision Maker: _____ PRINTED NAME of Participant

WHEN YOU INTEND TO SEEK BROAD CONSENT FOR FUTURE SECONDARY USE OF DATA/SPECIMENS

If you wish to ask participants to provide broad consent for future use of data (See Section 25.17), please provide initial boxes before the "Participant's Signature" block for participants to accept or decline to have their data/specimens used in the future. See example below:

CONSENT FOR FUTURE USE

Please initial next to your selection:

___ I agree to have my data [and/or specify biospecimen] used in future research studies

___ I do NOT agree to to have my data [and/or specify biospecimen] used in future research studies

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 initial next to your selection:

___ I agree to be contacted for future research studies

___ I do NOT agree to be contacted for future research studies

OPTIONAL INFORMING OF PRIMARY HEALTHCARE PROVIDER

Please initial next to your selection:

___ I agree for my primary provider to be informed of my participation

___ I do NOT agree for my primary provider to be informed of my participation

I have explained to the above-named participant the nature and purpose, the potential benefits, and possible risks of participation in this study. All questions that have been raised about this study have been answered.

_____	_____	_____
Signature of Person Conducting the Consent Discussion	PRINTED NAME & ROLE	Date

[Institutional Logos as applicable: Western, LHSC, LRI, **NO sponsor or funder logos**]

The following attestation must be provided if the participant is unable to read or requires an oral translation:

If the participant is assisted during the consent process, please check the relevant box and complete the signature space below:

☐ The person signing below acted as an interpreter, and attests that the study as set out in the consent form was accurately sight translated and/or interpreted, and that interpretation was provided on questions, responses and additional discussion arising from this process.

_____	_____	_____
PRINT NAME of Interpreter	Signature	Date

_____
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 the participant, and any questions have been answered.

_____	_____	_____
PRINT NAME of witness	Signature	Date

_____
Relationship to Participant