Notice: Do not save for reuse

You must download a new ICF template, for each new application, to account for updates to this form. [Remove this box]

Informed Consent Form (ICF) for Prospective Research with Human Participants-HSREB

This Informed Consent Form (ICF) Template has been designed to meet current regulatory and ethical standards.

# Important things to remember when completing your consent form:

* You must add all relevant institutional logos into the header.
* You will add a version date in the footer. Only one version date should be listed. This document version date will be listed on the approval letter from the Research Ethics Office (REO).
* You will use the term “participant”, not “subject”.
* You should use plain (lay) language at a grade 6-8 reading level ([instructions for assessing reading level](https://support.microsoft.com/en-au/office/get-your-document-s-readability-and-level-statistics-85b4969e-e80a-4777-8dd3-f7fc3c8b3fd2#:~:text=In%20your%20Word%20document%2C%20select,reading%20level%20of%20your%20document.)).
* You must fully write out all acronyms and abbreviations when they are first used.
* You must make sure the size and font of the text are consistent (Open Sans, black, 10pt, as per [Queen’s Brand Central](https://www.queensu.ca/brand-central/visual-identity/typography)).
* You must check that page numbers in the footer are correct after you have completed the form and removed all unnecessary sections (including these instruction pages).

# Instructions for how to use/modify/alter this template:

* **Text in black**

You should not remove or alter headings and text that are in black. This text represents Queen’s University’s approved template wording, that should not be altered without justification.

* Text in a black box with a grey background

These areas indicate instructions specific to a heading/section/area of text. Once you have added your information to that heading/section/area please remove the instruction box.

* Text in a dashed outline with a yellow background

Provides you with a prompt to adapt/alter that area of text to reflect your research study (i.e., add contact information, specify, or choose from several options). If the text is applicable to your study, you must change it to black text with no background colour. If the text is not applicable to your study, please delete it.

**How to change your text to black and remove background colour**

1. Select the paragraph/text you wish to change.
2. Under **Home>** **Styles>** right click **Normal**, left click **Modify.**
3. Ensure **Formatting** is set to Open Sans, 10, Automatic. Click OK
4. Left click on **Normal** to select Style.
* **Headings in blue text with a pale blue background**

Provides you with a Heading for sections that include suggested text. You should only use these if relevant to your study. If the heading is applicable to your study, you must change it to black text with no background colour. If the Heading is not applicable to your study, please remove it.

**How to change your Heading text to black and remove background**

1. Select the Heading you wish to change.
2. Select the **Shading** dropdown , select **No Colour**.
3. With the Heading still selected, select **Font Colour** , select **Automatic**.
* Text in blue with a pale blue background

Provides you with suggested text/example that you should use only if relevant to your study. If the text is applicable to your study, you must change it to black text with no background colour. If the text is not applicable to your study, please remove it.

**How to change your text to black and remove background colour**

1. Select the paragraph/text you wish to change.
2. Under **Home>** **Styles>** right click **Normal**, left click **Modify.**
3. Ensure **Formatting** is set to Open Sans, 10, Automatic. Click OK
4. Left click on **Normal** to select Style.
* Text in red

Indicates items required for studies funded or supported by a US Federal funding agency. If it is applicable to your study, keep the Headings/text and change it to black text with no background colour (follow the same steps as described above for blue Headings/text).

If the Headings/text are not applicable to your study, please remove them.

These pages provide you with directions for navigating/altering this document/form.

You must remove these pages when you have completed the form. [Remove this instruction box]

Summary of Informed Consent Form

This section is only required for US-regulated studies. Remove this section, Summary of Informed Consent Form, if it does not apply to your study.

For **all other studies,** begin on the page titled **Informed Consent Form (ICF) for Prospective Research with Human Participants-HSREB**

[Remove this instruction box]

Study title**:** Insert study title as written in protocol

Below is a summary of the key information about the study. Following the summary is the informed consent form that contains more information about this study. The research team will also talk to you about the study, and you can ask any questions.

Participation is voluntary, and you can decline to participate in any aspect of the research without penalty.

# Study purpose

The purpose of this trial is to provide a brief description of the reason why this research is being done, in 3 sentences or less.

# Duration

Your participation in this study is expected to last indicate anticipated number of weeks, months, or years. Participants will be followed for provide duration in weeks/months, or years.

# Study procedures

You must briefly describe the interventions and highlight any key procedures, especially any that will be long/burdensome. Point form is acceptable. [Remove this instruction box]

# Risks

Participation in this study may involve risks. The risk(s) you are most likely to experience is/are: specify risk(s) and expected frequency/(ies). The most serious risk(s) is/are: specify risk(s) and expected frequency/(ies). All risks are described in the informed consent form.

# Benefits

You must specify if there are direct benefits for participants or not. Specify if the possibility of direct benefit is unknown. [Remove this instruction box]

# Alternatives

You do not have to participate in this trial to receive medical care. If you choose not to participant in this study, you will receive the standard of care or you will be presented with other non-study related options. Please discuss these with your healthcare provider.

Informed Consent Form (ICF) for Prospective Research with Human Participants-HSREB

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This Content list is to help you navigate this form.

You must remove the Content list when you have completed the form below. [Remove this instruction box]

Informed Consent Form (ICF) for Prospective Research with Human Participants-HSREB

**Study title:** Insert title as written on the protocol

**Short title:** Insert a simplified title (if applicable)

**Principal Investigator:** Insert name, department, and telephone number

**Co-Investigator(s)/Supervisor:** Insert name(s)

**Sponsor:** Insert name

**Funder:** Insert name (if different from sponsor)

# Introduction

As a Substitute Decision Maker, you are being asked to provide informed consent on behalf of a person who cannot provide consent for themselves. If the participant gains the capacity to consent for themselves, your consent for them will end. Throughout this form, “you” means the person you are representing.

You are invited to participate in a research study because you add study specific information (i.e., have been diagnosed with x). This consent form provides information to help you make an informed choice. Please read this document carefully and ask any questions you may have. You can discuss your participation with friends, family, Elders, or other healthcare providers before choosing. All your questions should be answered before you decide whether to participate in this research study. This study received ethical approval by the Queen’s University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB).

Participation is voluntary, and you can decline to participate in any aspect of the research without penalty/any impact on your academic standing/any penalty or impact on your medical care/any impact on your employment. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

# Conflict of interest

You must include information about the presence of any real, potential, or perceived conflicts of interest/personal benefits to the researchers and the possibility of commercialization of research findings. If there is a conflict of interest, mitigation strategies must be clearly outlined.

[Remove this instruction box]

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

Or

Insert name has a conflict of interest to declare related to this study. Details are as follows: insert details.

# Background

You need to describe the background information and the reason why this study is being done.

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

[Remove this instruction box]

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).

Or

Health Canada has allowed insert name(s) of product/agent/device to be used in this study.

# Purpose of study

The purpose of this research study is describe the purpose in simple language.

# Alternatives

You do not have to participate in this study to receive medical care. Other options may include, but are not limited to:

You must list all standard of care treatments. If there are none, specify palliative or best supportive care or other research studies which may be available. [Remove this instruction box]

* begin list here
* The standard of care (SoC) is defined as the care/treatment most people get for specify condition. The standard of care in this case is: specify standard treatment(s).

Talk to your study doctor or other medical providers about the benefits and risks of these other options.

# Who will take part in this study?

For this research study, it is expected that specify number of participants will be recruited overall with specify number of participants from this site.

If you choose to take part in this study, your time commitment is specify total time commitment over specify amount of time weeks/months/years. This study should take specify time to complete and the result will be known in about specify time.

# Assignment to a group

This study is randomized, which means that you will be assigned to a group. You will not choose the group you are assigned to, this process is done randomly, like flipping a coin. The groups you could be assigned to are:

Group 1: specify each study group.

Group 2: specify each study group.

You will have add probability of randomization chance of being placed in either/any group.

The placebo used in this study looks exactly like the study drug, but it does not contain any active medication.

This study is a single blinded/double blinded study (see instructional text below).

You must choose either Single Blinded Study or Double Blinded Study from the descriptions below. Copy the text as written (select the text you want to copy and press Ctrl + C). Place your cursor outside of this instruction box (to paste the copied text press Ctrl + V). [Remove this instruction box]

Single Blinded Study: You will not know which group you are in, but the study doctor and study staff will know. OR You will know which group you are in, but the study doctor and study staff will not know.

Or

Double Blinded Study: Neither you nor the study doctors/study staff will know which group you are in. At the end of the study, when the results are known/ At the end of your treatment period will be informed which group you were assigned to. In case of an emergency, the blind can be lifted to treat you appropriately.

# Study procedures

This research study will take place at include name of study site.

Your participation in this research project will include add number visits. Each visit’s time commitment will be specified below.

During this study, the study doctor, a member of the research team, or yourself will perform the following tests or procedures:

You must describe all study procedures and specify which are experimental (outside of standard of care). Include the number of visits and duration of each visit. This can be done in two ways: separated by visit or by listing all non-experimental and experimental procedures. For easy reference and understanding by participants you should use a bullet point list (only use a numbered list if the procedures listed are meant to be completed in a specific order). A chart of events can also be used. See 8.3.1 Procedure definitions below. [Remove this instruction box]

## Non-Experimental Procedures:

The following procedures will be done as part of the study. Some of these may be part of the standard of care, however they may be done more frequently than if you were not in the study:

You must list the procedures in simple language and the time commitment for each. These can be listed by visit, in point form. If a study procedure is done as part of standard of care, but listed as data that will be collected for the purposes of this study, please clearly state that these procedures are standard of care but information from them will be included in the study data. [Remove this instruction box]

* begin list here

And/or

## Experimental Procedures:

The following tests are considered experimental, and will only be done as part of this study:

List all experimental procedures in simple language and the time commitment for each. These can be listed by visit, in point form. [Remove this instruction box]

* begin list here

And/or

## Visit 1:

You must list all procedures, in simple language, and the time commitment for each visit. Ensure it is clear which procedures are experimental. These can be listed in point form. [Remove this instruction box]

* begin list here

| Procedure | Visit 1 timing of visit e.g. day 8 | Visit 2 | Visit 3 | Visit 4 | Visit 5 | Visit 6 | Visit 7 |
| --- | --- | --- | --- | --- | --- | --- | --- |
| List each procedure in simple language, procedures are described below | X(add duration of visit) |  |  | X |  | X |  |
|  |  |  |  |  |  |  |  |

For each procedure, mark each participant visit with an ‘X’. [Remove this instruction box]

Below are the Procedure definitions and specific information for you to include in the table above. Use the procedure description as written, change only yellow highlighted text to include your study specific information.

1. Add rows to the table above, one for each procedure you are including.

2. Change only yellow highlighted areas to your study specific information.

3. Copy the text below (select text and press Ctrl + C).

4. Paste copied text into the table under the heading Procedure (to paste the copied text, press Ctrl + V).

5. Remember to change text to Open Sans, black, 10pt, no background colour, as per Queen’s Brand Central.

[Remove this instruction box]

### Procedure definitions

**Focus groups**

You will be asked to attend specify number focus group(s) at specify time point. A focus group is a small group of people who are asked to speak about their opinions on specify topic of focus group. The focus group will take place at specify location or virtual platform and be specify time frame (minutes, hours, days, etc.) long. The focus group will be recorded (specify audio, visual or both) and then later transcribed by include if this is done by a member or the study team, a transcriber that has signed a confidentiality agreement or the name of an online platform. For information about the security and privacy of this software refer to the confidentiality section of this form. When the focus group is transcribed, the participants’ information will be de-identified, by replacing your name with a unique participant ID in the transcript. Please note, while the researchers can assure their own confidentiality of information, we cannot guarantee that privacy will be maintained by the other participants. In addition, withdrawal of your data may not be possible if your responses compromise information provided by other participants in the group.

**Questionnaires**

You will be asked to respond to specify number of questionnaires at each time point (i.e., Visit 1, 2, etc.) as part of this study. These questionnaires will be completed specify the platform being used or if they will be completed on paper and will take about indicate time to complete. Some of the questions may be personal. If any questions make you uncomfortable, you may choose not to answer. Your responses will not be reviewed by your health care team.

**Participant diaries**

You will be asked to keep/fill out a diary specify how often they should complete. Please record specify what they need to do.

You will fill out this diary using specify how these are being completed (i.e., on paper or using a device online or mobile application). For information about the security and privacy of this software refer to: [insert web link here] OR if this is a Queen’s ITS approved platform, state: This platform meets Queen’s ITS standards.

You will be asked to return this diary specify when and where if applicable.

**Central review for** radiology/radiotherapy/surgical review/other

Your specify what is being sent for central review will be collected as part of this study and sent to specify location for explain why this is being done. These specify what is being sent will be kept specify time after which they will be specify what happens after. Your data will be sent/stored/retained (specify the details). Specify the information and the level of identifying information that will be sent.

**Mandatory sample collection**

As part of this research study, the following samples will be collected:

You must list each type of sample that is being collected, at what time points, and how much.

You need to specify the reason why these samples are being collected and include the method of collection.

Specify where these samples are being sent/stored, for how long, and how the samples will be destroyed.

For easy reference and understanding by participants, you should use a bullet point list (only use a numbered list if the information listed is meant to be understood in a specific order).

Sample text:

 • Tissue Samples: You must have a biopsy sample taken for this study. Insert information about each type of sample as applicable including when the sample will be taken (e.g., before study drug at each visit and the amount of sample being taken).

For US FDA-regulated studies: Include a statement that the participants’ biospecimens may be used for commercial profit and if the participant will (or will not) share in the commercial profit (as applicable)

[Remove this instruction box]

* begin list here.

**Sample identification**

To protect your identity, the information that will be on your samples will be limited to specify which identifiers will be on the samples. Despite protections being in place, there is a risk of unintentional release of information.

**Genetic testing**

This study involves genetic testing. Genes carry information about you and your family, from the colour of your eyes, to health conditions for which you may be at risk. This study will involve whole genome sequencing, which means all the DNA in your genome. Specifically, this study will test specify what is being tested.

The results of this genetic testing could impact you and people biologically related to you, including your biological family. Your genetic information can identify you and could be used to identify your relatives. Despite protections being in place, there is a risk your genetic information could be released by accident. There is no way to predict what effects such an information loss would have. Even though this risk is unlikely, we think you should be aware. You will/will not be told about the results of your genetic testing.

If you are a First Nations or an Indigenous person who has contact with Elders, you may want to talk to them before you decide about this research study. Elders may have concerns about some research procedures, including genetic testing.

**Optional study procedures**

This study also has an optional component.

You need to briefly describe the optional study procedures. For easy reference and understanding by participants you should use a bullet point list (only use a numbered list if the information listed is meant to be understood in a specific order). [Remove this instruction box]

For this study, completion of:

* begin list here.

Detailed information regarding the optional study is explained at the end of this consent form.

If you wish to participate in the optional study procedures, then please indicate your consent below. Whether you decide to participate in the optional part of the study will not impact your participation in the rest of the study.

**Withdrawal of samples**

You must describe the process for withdrawal of samples, including who participants should contact. Include any limitations to the withdrawal and the reason for the limitation (i.e., sample will be used up, anonymized). [Remove this instruction box]

If you agree to take part in the study, signing this consent form means that you are consenting to the collection of your specify bio samples being collected for this study sample together with any related health information from the hospital or clinic where it was collected.

These samples will be sent to a laboratory at the specify the institution, city, country (note: minimum required location is country). The retention period is specify the retention period in days/weeks/months/years. If you no longer want your samples to be used in this research, you should tell the study team. The study team will ensure the samples are returned to the hospital/clinic from which they were obtained if needed or destroyed. 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.

# Risks

There are no known risks to this study.

Or

The risks and side effects of the standard procedures will be explained as part of your standard of care and therefore are not listed. You may experience some risks or side effects during your participation in this study. The known risks are listed below, however, there may be other unexpected risks that are not known. You will be informed during the study of any new risks that may impact your willingness to participate.

You must list all known risks. For medication side effects, list the likelihood of each risk in a chart format. Suggested categories are:

Common (21%-100%)

Occasional (5%-20%)

Rare (1%-4%)

You must also list any serious risks. For newer medications, consider specifying how many participants have taken this medication. You need to include risks associated with mandatory sample collection and imaging. SoC risks do not need to be included as these will be presented to the participant regardless of participation in this study. You should only include study related risks in the consent form. [Remove this instruction box]

* begin list here.

## General risks

If you choose to take part in this study, there is a risk that the study drug(s)/study approach could result in specify the general risks of this study intervention.

## Mandatory sample collection risks

The list below shows the most common side effects with specify the mandatory sample collections.

* begin list here.

## Imaging risks

You must include imaging risks of radiation that are above the standard of care (i.e., for purposes of this study). [Remove this instruction box]

The risks associated with the imaging procedures specify the imaging procedures in this study are:

* begin list here.

## Drug risks

If applicable, include a brief summary of the most common and most serious side effects doctors know about. (See below for possible side effects of study agents list).

## Possible Side Effects of Study Agent

**Common, some may be serious** 21%-100%

* begin list here.

**Occasional, some may be serious** 5%-20%:

* begin list here.

**Rare** 1%-4%:

* begin list here.

## Reproductive risks

Include information about the known or unknown reproductive risk for participants and their partners. Include information about pregnancy testing and what will happen if the participant or their partner becomes pregnant. NOTE: if conducting research at Hotel Dieu Hospital (HDH) and/or Providence Care Hospital (PCH) please see below for mandatory language [Remove this instruction box]

The specify intervention used in this study could be very harmful to an unborn or newborn baby. There may be some risks that doctors do not yet know about. It is very important that you check with your study doctor about methods to prevent pregnancy to use during the study and for insert time in months/yearsafter you have completed the study or the last dose.

If you or your partner become pregnant during this study, you must inform the study doctor immediately. The study doctor will ask you and/or your partner to provide information about the pregnancy. If your partner becomes pregnant, they will be asked to sign a separate consent to give permission to collect information about their pregnancy. You or your partner can decline to give permission to collect this information. You may also withdraw consent at any time without a reason.

If you are conducting research at: Hotel Dieu Hospital (HDH) and/or Providence Care Hospital (PCH), include the following information about the known or unknown reproductive risk for participants and their partners. Include information about pregnancy testing and what will happen if the participant or their partner becomes pregnant or fathers a baby. [Remove this instruction box]

The effects that insert name of product/agent/device may have on an unborn baby (fetus) are unknown. You must not become pregnant or father a baby specify period e.g., while taking [insert name of product/agent/device] and for [identify post-intervention period] after the last dose. The study doctor will discuss family planning with you to ensure that you do not become pregnant or father a baby during the study. If there are known interactions or contraindications with specific methods, they should be included.

# Benefits

You must include information about potential benefits to participants (if none, state this) and in general, for the entire population. [Remove this instruction box]

There are no direct benefits to you for taking part in this study/You may or may not benefit from taking part in this study/The expected benefit(s) from participating in this study are/is (specify).

We hope that the results of this study may benefit specify in the future.

# What are your responsibilities?

If you decide to participate in this study, you should:

You need to list all the requirements for participants in this study, including any activities or medication that are not permitted during the course of the study and all the study procedures participants are required to do (i.e., diary completion, study drug compliance, etc.). [Remove this instruction box]

* begin list here.

# Incidental findings

There is a possibility that material/incidental findings/test results are made during your participation in this research study. These findings and/or results may be relevant to your decision to continue or withdraw from this study. You will/will not be informed of any incidental finding during the study.

# Withdrawal from this study

You can choose to withdraw from this study at any time without providing a reason. To withdraw your participation from this study please contact: specify who they should contact and how to ensure that you withdraw safely.

You may also withdraw the data that was collected about you from this study by specify who they should contact and how. Please note that this will mean (when you withdraw your data) that you are also withdrawing from the study.

You must include any limitations to this withdrawal of the data (i.e., can’t withdraw after submission of an anonymous survey/following publication). [Remove this instruction box]

 Or

**For clinical trials/if relevant, add:**

Information that was recorded before you withdrew will be used by the researchers for the purposes of the study, but no information will be collected or sent to the sponsor after you withdraw your permission.

## When can participation in this study end early?

The study doctor, sponsor, regulatory authority, or the research ethics board (REB) may stop your participation in the study early, without your consent, for the following reasons:

* Specify all the study specific stopping rules
* The Sponsor decides to stop the study.
* The Regulatory Authority(ies) or research ethics board withdraw permission for this study to continue.

# Confidentiality

All the information collected during the research study will remain strictly confidential to the extent permitted by the applicable laws. If you decide to participate in this study, the research team will only collect the information needed.

This will include collecting information from your medical record including specify the data being collected from participant medical records. Also specify if any other sources of data are being used for data collection (for example, academic records). By signing this consent form, you give permission for the research team to collect information from your medical record. In addition, the following information will also be collected for this study specify all identifiable and demographic data being collected. A copy of this consent form will be filed in your medical record. You will also have a copy of this consent form.

To protect your privacy, you will only be identified in the study documents by a participant ID. The master log linking your name/medical record number to your participant ID will be stored separately from other study data and will only be accessed by specify who has access. This master log will not leave the local site.

We would like to contact your primary care provider to inform them that you are part of this study. If you have a primary care provider and want them to be informed of your participation in this study, please provide consent along with their name and contact information below.

The study data will be stored:

* Specify storage for both paper and electronic study data.

If the study involves the use of non-Queen’s ITS-approved platforms you must add the following statement and edit it as appropriate (i.e., translation, transcription platforms, etc.).

[Remove this instruction box]

* Your participation in this study will involve sending your data list data here, facial images, audio recordings, video recordings, etc. to a third-party platform, insert name of platform here for the following specific purposes: list all purposes here. Visit the platform’s website insert third party’s privacy link here for information about the protection and use of the data. Once your data has been processed for the specific purposes mentioned above, it will be deleted from the third-party’s platform or state if the platform will retain the data and for what period of time, who has access to the data etc.

The following study data will not leave the local site:

* Specify what study data will be stored on-site or specify above that no data will leave the local site.

The following study data will be sent to:

* Specify what study data will be sent and where. Include information about any platform used to store data.
* Include information about data sharing and the potential for the generation of identifiable information if databases will be linked.

The study data will be stored for specify time period.

Upon study completion, all insert the format of data (i.e., de-identified) data used to develop the study results for publication will continue to be kept in a secure and encrypted location accessible only to the PI(s)/study team for at least 5 (as per Queen’s University Policy) or 15 (as per Health Canada Data Retention Policy) years. All other data will be deleted or destroyed. Once the data is no longer required for publication or research purposes (after a minimum of 15 years for Health Canada), it will be deleted by the PI(s)/specify.

For studies with data that can be de-identified, use: [Remove this instruction box]

For publication, the data used to generate the study results may need to be deposited in a research data repository. If this is required, only de-identified data will be deposited, and the study data stored elsewhere will be deleted. Study data deposited in a research data repository may be accessible to other researchers for future, similar studies. If you do not want your de-identified data to be available to other researchers for future, similar studies, please indicate that in your consent options.

For studies with data that CANNOT be de-identified, use: [Remove this instruction box]

For publication, the data used to generate the study results may need to be reviewed by other researchers as part of the peer-review process. If this is required, only peer-reviewers identified by publications (e.g., academic journals) will be provided with a copy of the data for review purposes only. Once the review is completed, they will no longer have access to the data.

The minimum retention period is 5 years per Queen’s policy. Health Canada regulated studies must retain data for a minimum of 15 years. [Remove this instruction box]

If indefinite data storage is required, that is not in a data repository, you need to specify arrangements for data custodianship. This might involve departmental oversight as a data custodian in the event of the current data custodian leaving Queen’s employment or following their death. [Remove this instruction box]

The data custodian(s) of the study data for the duration of the retention period is/are specify.

Note: For student projects, after a student graduates, the supervisor is responsible for managing the data and the disposal of data if it is not submitted to a repository. Research supervisors should be described as joint custodians of all research files and data while students are active in their degrees.

[Remove this instruction box]

There are organizations and their representatives that may look at or receive copies of some of the information in your study records and in some cases, your medical records, for data analysis and quality assurance for monitoring, control, safety, and security. These may include:

* Members of the study team, as delegated by the study doctor/principal investigator.
* Specify name, the sponsor of the study.
* Authorized Representatives of Queen’s University, its affiliated hospitals and/or Queen’s University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB).
* Health Canada, because they oversee the use of natural health products/drugs/devices in Canada.
* The U.S. Food and Drug Administration, because they oversee the use of natural health product/drugs/devices in the United States.
* Specify other organization(s) that may access study records/medical charts.

Note: For US studies: Include one of the following statements about collection of identifiable information or identifiable biospecimens:

Identifiers might be removed and the de-identified information or biospecimens used for future research without additional informed consent from the participant.

or

The participant’s information or biospecimens will not be used or distributed for future research studies, even if identifiers are removed.

The results of this research study data may be published or shared during scientific meetings however you will/will not be identified during the dissemination of study results or publication. All efforts will be made to protect your privacy, and the likelihood that someone may identify you is small, however it cannot be eliminated.

Quotes from some of the interviews/focus groups may be used when presenting study results. You can consent below whether or not you agree to the use of quotes (Note: If use of quotes is mandatory, remove this). These quotes will never include any real names with quotes and researcher will do their best to ensure quotes do not identify participants. During the interview/focus group, please let us know if you say anything you don’t want quoted.

# Information about this study

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

[Remove the red text if you are not doing a US FDA-regulated study]

[Remove this instruction box]

FOR US FDA-regulated studies, include a statement whether clinically relevant research results, including individual research results, will be disclosed to participants and, if so, under what conditions.

A description of this clinical trial will be available on [ClinicalTrials.gov](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.

Or

A description of this clinical trial will be available on insert web address. This website will not include information that can identify you. You can search this website at any time.

# Cost for participation

The cost of the insert drug/agent/device/invention will be covered at no cost to you while you take part in this study. After the study, please specify if the drug/agent/device/intervention will be available at a cost or not available and why. The cost of your medical treatment will be paid by your provincial health coverage to the extent that is available. There is no additional cost to you or any private health care insurance for participating in this study.

If there are additional costs to participants, you must specify what they are and the plan to handle these costs (i.e., see section on reimbursement).

[Remove this instruction box]

# Reimbursement

You will not receive any reimbursements for costs associated with taking part in this study.

Or

If you decide to participate, you will receive reimbursement for specified costs, as outlined below.

You must specify the amount, type of payment (gift card, cash, cheque), and method of payment. If using gift cards, you need to specify where the gift card can be used. If there is a payment plan, specify the payment schedule (i.e., payment per visit/stage of the study).Clearly state how compensation will be addressed if a participant withdraws early.

For reimbursement, you must specify what is being reimbursed, the maximum dollar amount and what participants need to provide to get this reimbursement (e.g., itemized receipts). [Remove this instruction box]

# Incentives

You must specify the method of incentives for participation, the amount, type of payment (gift card, cash, cheque), and method of payment. If using gift cards, you need to specify where the gift card can be used. If you will be using a draw, please refer to the guidelines on the REO website (https://www.queensu.ca/vpr/ethics/guidelines-policies) for required information to ensure your draw is legally compliant. See below for mandatory language to be included for a draw.

After submitting your survey responses, you will be directed to a separate survey and can enter your contact information to be entered into a draw for a chance to win prize. Your odds of winning are based on the number of individuals who participate in the survey.

Your name and email will be stored securely and separately from your survey responses and permanently erased once the draw is complete. The survey will close on date.

Entry into the draw will close on date/once all survey responses have been received.

The draw will take place x days/weeks/months after the survey closes and be conducted by impartial third party/random number generator.

Only one prize will be awarded per participant.

Winners will be contacted using the contact information provided upon entry into the draw. If a winner has not responded within timeframe, the winner will forfeit the prize, and another draw will be held to determine a winner. The prize must be accepted as awarded or forfeited and cannot be redeemed for cash.

Participation is not required for entry into the draw; to enter without participating in the study, insert information on how the participant can enter the draw without participating in the study. For example: “submit a 3x5 index card with your name and contact information, along with the study title, printed by hand to lab address. Entries must be received by the closing date above to be eligible. We are not responsible for lost, late, incomplete, illegible, damaged, destroyed, postage due, or misdirected entries. No bulk mailings will be accepted. All entries will become the property of the study team and will not be returned.”

# Research related injury

If you are injured as a result of participating in this study and need medical treatment, please talk with your study doctor immediately about your treatment options. Medical care will be provided in case of research injury or side effects, or you will be referred for appropriate medical care at no cost to you.

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

# Future studies

If asking permission to add name and contact information into a re-contact database for future studies, add the following (amend as applicable):

[Remove this instruction box]

In the consent section, you will be given the option to consent to your specify what data is being collected and entered into a re-contact database for future studies. Suppose you agree below to be part of the re-contact database. In that case, you may be contacted in the future about research studies in specify subject/area of research being conducted by this study team/department. Note:Consenting to future contact is not equivalent to consenting to participate in future studies. This recontact database is maintained by specify custodian and will be active for specify time period. You can withdraw from this database at any time if this is not the case, specify without reason by contacting add contact detail for this person.

If de-identified data or samples may be used or shared for future research (i.e., storage in a biobank), include the following:

[Remove this instruction box]

Your de-identified study data and/or de-identified specify what type of samples samples from this study may be used or shared with other researchers inside and outside of Canada for future studies.

Include the following if the data/samples will be stored outside of Canada:

[Remove this instruction box]

Your data and/or samples could be shared with researchers not subject to the same ethical guidelines as researchers from Canadian Institutions. De-identified means that identifiers such as name and date of birth will be removed and replaced by a unique participant/study ID. This may include storing the de-identified study data and/or specify what type of samples samples in controlled-access databases/biobanks, for which access is limited to researcher(s) who submit a study plan and who sign an agreement to use the study data and/or specify what type of samples samples only for that research. The master log matching your study data and samples with your name and other directly identifying study data will not be shared. The custodian of this database/biobank is (specify custodian), and it is expected that this database/biobank will be active specify time period. If you wish to withdraw from this database/biobank please contact (add contact details). Once your data and/or samples have been entered into the de-identified database, it will not be possible for you to withdraw them because (state reason). If you do not wish for your study data to be shared for future studies below, you can indicate this in the consent section below.

If you are depositing de-identified data in a publicly accessible repository:

[Remove this instruction box]

De-identified study data and/or the full coded data set may/will also be placed in an open access, publicly accessible repository add name of repository if known as may be required by scientific journals or funding partners.

# Contact information

If you have questions about this study or if you suffer a research-related injury, you can contact:

Specify name and contact details (include email address and/or phone number).

Students must include the name and contact information of their research supervisor(s).

[Remove this instruction box]

For ethics concerns, please contact The Queen’s University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB) at 1-844-535-2988 (Toll free in North America) or email HSREB@queensu.ca. For research conducted outside of North America use: 1-613-533-2988. If non-English speaking participants wish to contact the Chair for ethics concerns, translation assistance may be necessary, as the REB Chairs communicate in English only.

# Optional study

This part of the consent form is about optional studies that you can choose to take part in. Optional studies will either be directly related to the main study or will be for future research not related to the main study. These optional studies will not benefit your health.

The researchers leading this optional study/these optional studies hope the results will help other people with add details in the future.

Taking part in this optional study/these optional studies is your choice. You can still take part in the main study even if you say “no” to this study/any or all these studies. There will be no loss of benefits for saying “no.” If you consent but cannot complete this study/any of these studies for any reason, you can still take part in the main study.

## Optional study procedures

You must specify which procedures are experimental. Include the number of visits, duration of each visit and overall time commitment for these optional components. Use of subheadings or point form list is effective.

[Remove this instruction box]

## Optional sample collection

You need to list each type of optional sample collection sample that is collected, at what time points and how much.

Specify the reason why these samples are being collected. Include the method of collection and any risk(s) associated with this collection.

State mitigation strategies for these risks.

Specify where these samples are being taken.

Include information on how the samples will be identified, genetic testing and withdrawal for samples as applicable to the optional sample collection.

HSREB prefers that optional sample collection be included in the main consent however, if required by the sponsor, a separate consent form can be used. [Remove this instruction box]

# Consent and signatures

By signing this consent form, I agree that:

* I have read the Informed Consent Form.
* I have had all my questions answered.
* I have been provided a copy or directed to keep a copy of the ICF for my records.
* A signed copy of the ICF will be kept by the research team.
* By consenting, I have not waived any legal right in the event of research-related harm.

|  |  |
| --- | --- |
| I consent to participate in the main study | Yes [ ]  No [ ]  |
| I consent to audio recording | Yes [ ]  No [ ]  |
| I consent to video recording | Yes [ ]  No [ ]  |
| I consent to the use of quotes | Yes [ ]  No [ ]  |
| You can recontact me to inform me about future research projects that I may consider participating in. | Yes [ ]  No [ ]  |
| You have my consent to store my data and/or human biological materials for future unspecified research. | Yes [ ]  No [ ]  |
| You can contact my primary care provider to inform them that I am participating in this study. Name of primary care provider:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Contact information:\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Yes [ ]  No [ ]  |

Add consent checkboxes for any other aspects of the study. [Remove this instruction box]

|  |  |
| --- | --- |
| I consent to participate in the optional portion of this study | Yes [ ]  No [ ]  |
|  |  |
| For online checkbox consent or implied consent, remove all signature blocks as consent will be obtained by the participant completing the survey or by clicking the consent box.For implied consent add the following:Survey completion will represent consent. (include a link to the survey) [Remove this instruction box] |  |

When collecting verbal consent (i.e., no signed consent forms), remove the signature portion of the participant/Substitute Decision-Maker below and complete the verbal consent log as documentation of consent. Retain the Signature of the Person Conducting the Consent Discussion. [Remove this instruction box]

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of Participant | Printed Name | Date |
|  |  |  |
| Signature of Participant/Guardian/Substitute Decision-Maker (if applicable) | Printed Name | Date |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of Person Conducting the Consent Discussion | Printed Name | Date |

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.

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
| Signature of Translator | Printed Name | Date | Language |

☐ The consent form was read to the participant. The person signing below attests this study was accurately explained to the participant, and any questions have been answered.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of Witness | Printed Name | Date |

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