**Remove this page before submitting**

**Instructional Notes for the Interventional Informed Consent Form Template – 2021**

**(These notes are instructional and should not be included in the informed consent form submitted to the REB or given to the prospective research participant.)**

* This informed consent form (ICF) template is intended for use by investigators, study coordinators, or informed consent form authors when drafting ICFs. It has been designed to meet current regulatory and ethical standards, while using language approved by the Nova Scotia Health (NS Health) REB.
* Please read these guidelines carefully before submitting your application to the research ethics office. The REB requests that all ICFs follow the prescribed structure and format as set out in this template to facilitate REB review.
* All ICFs submitted to the REB must adhere to the requirements of the NS Health REB and the [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) 2018 ed.](https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html)  All ICFs for clinical trials that have been submitted to Health Canada or the Food and Drug Administration (FDA), and Phase IV trials (i.e. post-marketing), must also follow the [International Conference on Harmonization (ICH) Guidance E6: Good Clinical Practice (GCP): Consolidated Guideline](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6-eng.php).
* Sections may be omitted if they are not relevant to the specific protocol. Ensure sections are properly renumbered. The section headings should also follow the order suggested in this template.
* Please ensure you are gender neutral by using male/female/other for sex and 'they' as a pronoun rather than 'he/she.'
* *Instructions are in red italics*, examples are in green for use in the ICF. This template will serve you best if it is viewed electronically or printed in color. All red text should be edited appropriately for the specific protocol. After all edits have been completed, convert the text to black.
* Before submitting the ICF to the REB for review, take the time to review carefully for spelling, grammar and formatting issues that may have arisen during editing of this template.

Informed Consent Form Interventional Studies Template

|  |  |
| --- | --- |
| **STUDY TITLE:** | *Same as the Protocol and REB application* *When the title is cumbersome, a short simplified title may be included in addition to the Full Study Title.* |
| CLINICAL STUDY REGISTRATION NUMBER: | *All clinical trials must be registered before REB approval as per EAF Form A9) (e.g. clinicaltrials.gov)* |
| PRINCIPAL INVESTIGATOR: | *Name, department, address and telephone or pager number*. |
| STUDY SPONSOR: | xyz Pharmceuticals… *Must match the EAF* |
| FUNDER: | This study is being funded by… *Must match the EAF* |

# Introduction

You have been invited to take part in a research study. A research study is a way of gathering information on a treatment, procedure or medical device or to answer a question about something that is not well understood. Taking part in this study is voluntary. It is up to you to decide whether to be in the study or not. Before you decide, you need to understand what the study is for, what risks you might take and what benefits you might receive. This consent form explains the study.

*If**time permits:* You may take as much time as you wish to decide whether to participate. Feel free to discuss it with your friends and family, or your family doctor.

*If time is limited:* The research team will tell you if there are any study timelines for making your decision.

Please ask the research team or the principal investigator to clarify anything you do not understand or would like to know more about. Make sure all your questions are answered to your satisfaction before deciding whether to participate in this research study.

The researchers will:

* Discuss the study with you;
* Answer your questions;
* Be available during the study to deal with problems and answer questions.

*Include a statement indicating why a person was flagged as a possible candidate for inclusion in the trial*. You are being asked to consider participating in this study because you have condition X / are about to undergo procedure Y procedure OR are a healthy individual / are a nurse.

If you decide not to take part or if you leave the study early, your usual health care, employment evaluations, etc. will not be affected.

# Why is there a need for this study?

*Explain in lay terms the background information for the study referring to knowledge to date (i.e. why it is being undertaken. Why is this new drug, device, or procedure being tested and why it might help)*

*See suggestions below to assist you with defining the purpose of this study.*

* ***Phase I****- These trials test an investigational product or test article on a small group of people for the first time. The purpose is to:*
  + *assess the investigational product or test articles safety*
  + *find out what a safe range would be for dosage*
  + *identify side effects*
* ***Phase II****- The investigational product or test article is given to a larger group of people (usually 100 or more) to:*
  + *obtain preliminary data on the effectiveness of the investigational product or test article for a particular disease or condition*
  + *further assess the drug's investigational product or test articles safety*
  + *determine the best dose*
* ***Phase III****- The drug investigational product or test article is given to even larger groups of people (usually 1,000 or more) to:*
  + *confirm its effectiveness*
  + *monitor side effects*
  + *compare it to commonly used treatments*
  + *collect information that will allow the investigational product or test article to be used safely on the market*
* ***Phase IV****- These trials are done after the drug is approved and is on the market. They gather information on things like the best way to use a drug, and the long-term benefits and risks.*

# What Is Being Tested?

*Provide information regarding the issues below*:

* *Is the treatment deemed experimental?*
* *Has Health Canada, the FDA or other regulatory authorities approved the treatment?*
* *Has there been animal testing? (include animal data for Phase I studies and Phase II studies when study drug has a high terogenicity)*
* *How many people have been tested, to date?]*

The following Health Canada information, modified as necessary, for drug or device studies:

Health Canada has not approved the sale or use ofinsert study drug/deviceto treatinsert disease, including stage of disease where relevant, for example, for cancer,although they have allowed its use in this clinical trial.

Or,

Health Canada has approved the sale or use of insert study drug/deviceto treattype of disease, although they have not approved its use for this disease/stage of disease, or at this dose, etc., they have allowed its use in this clinical trial.

# How Long Will I Be In The Study?

*State how long the participant will be involved with the study (e.g. – the length of time over which the study visit(s) will occur) and the approximate overall amount of time that the study activities will require of participants (if possible).*

*If your study involves one or more substudies, if at all possible please state the approximate amount of additional time this will require from participants, over and above the time required for participation in the main study.*

The length of this study for participants is duration of time for participants in weeks, months or years. The entire study is expected to take about total length of study in months or years to complete and the results should be known in # of years.

# How Many People Will Take Part In This Study?

It is anticipated that about # of global (worldwide) participants people will participate in this study throughout region NS, Canada, worldwide, etc. About # of local participants people will participate in this study at name of institutions.

# How Is The Study Being Done?

*Describe treatment/intervention by study group and the probability of assignment to each study group. Include general information on completing questionnaires and/or keeping diaries and the probability of assignment to each study group. See suggestions below. If these suggestions are not applicable, provide a detailed description appropriate to the specific protocol. For studies with more than two study groups, consider using a study plan or schedule of assessments similar to the examples at the end of this document.*

*For clinical trials involving placebo, describe any therapy that will be withdrawn or withheld for purposes of the research study, and the anticipated consequences.*

Double-Blinded, Randomized Studies:

Participants in this study will be randomly (by chance) placed in one of (total number of study groups) study groups. Neither you, the study staff nor the investigator(s) can influence or will know which group you are in. However, in case of an emergency the study treatment can be identified. You will have a (%) chance of being placed in [select one] any/either group.

Placebo, Double-Blinded, Randomized Studies:

This is a placebo-controlled study. A placebo is a product that looks like the test article but does not have any active or medicinal ingredients. The placebo in this study will be the same shape, size and colour of the investigational product/test article but is not expected to have any effect on your (condition). A placebo is used to eliminate bias in the study, making the results of the study more reliable. Participants in this study will be randomly (by chance) placed in one of the two study groups (DRUG (including trade name) or placebo). Neither you, the study staff, nor the investigator(s) can influence or will know which group you are in. However, in case of an emergency, the study treatment can be identified. You will have a (%) chance of getting a placebo during the entire study.

Single-Blinded Studies:

Neither you, the study staff nor the investigator(s) can influence which group you are in. You will not know which group you are in, but your research team will.

Open-Label, Randomized Studies:

Participants in this study will be randomly (by chance) placed in one of (total number of study groups) study groups. Neither you, the study staff, nor the investigator(s) can influence which group you are in. You will have a (%) chance of being placed in [select one] any /either group. You and the research team will know which group you are in.

*The specific study activities and/or procedures that participants will take part in or undergo will be covered in the next section.*

*If blood will be drawn as part of the study, provide an indication of the total amount of blood (in tablespoons/teaspoons and ml) to be drawn during the study from each participant. State the total anticipated time commitment for participation and the total number or frequency of visits/contacts.*

You will be asked to return to the hospital for # of visits over the next # of months.

*If your study involves one or more substudies, please provide a brief overview in lay terms of how you will be conducting each of the substudies.*

# What Will Happen If I Take Part In This Study?

Name and explain each of the procedures/responsibilities as the research participant will experience it in lay terms. Clearly explain if there are parts of the study which a participant can choose not to participate in. It is helpful to separate the study phases under specific headings (i.e. screening, baseline, randomization, follow-up, etc.) and to include the purpose of the visit. If similar tests are done on multiple visits, try to minimize redundancy by grouping visits together.

*If your study involves one or more substudies, please describe what additional research activities this will entail for each of the substudies. In addition, this information should be added to the study table (if applicable).*

*Please omit any procedures or activities that are considered standard of care. These procedures will be covered in the clinical consent for treatment.*

Whenever possible, please use a table like the one at the end of this template to describe the study procedures. Please ensure that any study tables are contained on one page instead of spreading across several pages. If the study only involves one study visit and only a couple of procedures or activities take place at the study visit, a table is not required.

*Details to consider:*

* *What will happen at each visit/contact point with the investigator including by telephone/letter (i.e. procedures, tests, questionnaires, interventions, treatments and interviews). The more invasive the procedures, the more detail should be provided. If a questionnaire is to be completed, provide a description of the questionnaire/types of questions that will be asked, how long it will take to complete, and that the participants choose not to answer any questions. Repeated explanations are not necessary, so only explain at first instance.*
* *The need for "washout" of any treatment that the participant is currently taking and the potential risks/discomfort.*
* *Information regarding audio/videotaping and explicit options to consent (or not) to recording.*
* *Any follow-up contacts by telephone or mail and what is involved and how long each will take.*

Details about the collection of human biological materials (i.e. tissue, organs, blood, plasma, urine, saliva, other bodily fluids, embryos, fetuses, fetal tissue and human reproductive material):

* *Specify whether the collection of samples/tissues is optional (i.e. for a sub-study directly related to the main research study) or mandatory for study participation.*
* *When collection of the sample/tissue is required, state* The collection of *type of sample* is a necessary part of this study.
* *OR when optional, state:* You may decide not to have your *type of sample* collected and still participate in this study. *And use the check boxes on the signatory page.*
* *What the sample/tissue is to be used for (i.e. current research study, commercial use (for profit) or future unknown research/banking)*
* ***The type and amount of sample/tissue to be taken, the manner in which sample/ tissue will be taken, the safety and invasiveness of acquisition;***
* ***The conditions of preservation of the sample/tissue.***

##### SCREENING *(if no screening tests are required for participation, please omit)*

If you want to be in this study and sign this consent form, you will be asked to do some tests to see if you can take part. This is called screening. The tests may show that you can't be in the study. There may be other tests done as part of usual care. The research team will discuss these with you.

You will have to undergo the following screening tests:

List screening tests, either in a bulleted list or in paragraph form.

STUDY

We will do the following as part of the trial:

* *List study procedures, either in a bulleted list or in paragraph form*
* *If testing for HIV, HEP B, and Hep C; it must be stated that all positive results will be reported to the Provincial Health Authority as required by law.*

FOLLOW UP

When the study is finished or if you decide to stop participating, you will be asked to have the following tests and procedures done:

* *List study follow-up procedures, either in a bulleted list or in paragraph form*

***IMPORTANT:*** *Explicitly state that participants are free not to follow any or all of these procedures following withdrawal from the research.*

Of course, you may ask not to have further tests done or to participate in any additional study procedures at any time.

You must tell the research team about any treatment therapies, drugs or medicines you are taking or wish to take. You must also tell the research team about anything unusual that is happening with your health. This includes any medical problems that seem to be getting worse. If you have to see another doctor or have to go to a hospital, you should let the doctors know that you are in a research study. You should also tell your own doctor as quickly as possible, for your safety.

*See end of this document for a sample Study Plan and Schedule of Assessments.*

# What About Birth Control and Pregnancy?

*Please include this section* ***(as per*** [***TCPS 2 Article 3.2 (c)***](http://www.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#toc03-1a) ***and*** [***ICH GCP Section 4.8.10 (g***](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6-eng.php)***)*** *only if pregnancy is an exclusion criterion, or there may be risks to those who are pregnant, become pregnant or those who are nursing mothers, were they to participate in the study. Otherwise please omit this section from the consent form.* **(REMOVE THIS TEXT IN YOUR FINAL VERSION – IT IS FOR YOUR REFERENCE ONLY)**

*IMPORTANT: Make sure you adjust the wording of the 1st and 3rd paragraphs appropriately to refer to the treatment being tested.*

*NOTE: If dual birth control methods are required due to the terogenecity of the study treatment, please amend the suggested wording as required to address the issue.*

The effects of the study treatment on unborn babies or sperm are unknown. You should not take part in this study if you are pregnant or planning to become pregnant. Males should not father children while in this study. The medicine a mother takes while breastfeeding can also pass into a nursing child through breast milk. In this case, there is a possibility of causing harmful side effects to the child. The safety of study treatment during breastfeeding is not known. For this reason, breastfeeding female cannot take part in this study.

***Birth Control*:** If you and your partner are of childbearing potential (physically able to have children) and are sexually active, you must practice an acceptable birth control method during this study and for # of months after you have stopped taking the study treatment to prevent pregnancy. Avoiding sex (abstinence) is OK for this trial. Other acceptable birth control methods include tubal ligation (tying the tubes), vasectomy, intrauterine devices (IUD), hormonal implants, injectable contraceptives, and using barrier methods such as condoms, vaginal diaphragm with spermicide, or sponge. If you have questions regarding appropriate birth control for you, please discuss with your family doctor.

***Pregnancy****: Please notify your research team* if you get pregnant or father a child during the study. You may need to stop participating in the study if you or your spouse become pregnant. If necessary, we will ask your permission to refer you to a doctor to look after your pregnancy. If you have a baby, we may also ask if we can study your health records and the baby's to make sure the study treatment has not had any bad effects. If you father a child while in the study, your pregnant partner may be asked if we can study her health records and the baby's to make sure the study treatment has not had any harmful effects.

# Are There Risks To The Study?

Describe the reasonably foreseeable risks, harms, discomforts and inconveniences to the participant and how these will be managed.

* How much experience has been accrued with new drug(s)/device/procedure?
* Separate the risks by study drug, procedure or intervention as appropriate.
* Address incidence/frequency, severity, and long term impact/reversibility.
* Provide the frequency of events in descending order.
* Ensure risks include the likelihood of occurrence (i.e. 4 out of 10 (or 40%) of people experiences…)
* Always write out terms like "less than" or "greater than", as some people will not understand or misinterpret symbols such as "<" or ">".
* Any serious side effects or risks such as stroke, heart attack or death should be listed in a separate paragraph and not buried in the text, or listed first if using the table format.
* Include psychological and emotional risks such as anxiety, distress, embarrassment, or feelings of sadness that may arise from questionnaires and interviews about sensitive issues.
* The risks of questionnaires/surveys and blood sampling need to be stated (our standard wording for these risks are cited below; include if applicable to your study).
* Statement concerning study interventions with other treatments (if applicable).
* *If your study involves procedures that will expose participants to radiation or you require services from the Radiology/Diagnostic Imaging Department (i.e. MRI), please fill out the Radiological Review Application – Research Involving Radioactive Material or Radiation Emitting Devices Form and include it with your original submission to the board, and include the wording requested by the Radiation Safety Program (on page 2 of the above-noted document) within this section of the consent form. Please note that this form must be filled out and provided with your original submission, and relevant risk wording provided must be included in the consent form if participants will be exposed to more radiation than they would receive as part of standard medical care.*

***NOTE: Only list the harms of the research aspects of the trial. Risks Stand of Care procedures will be covered in the consent for treatment.***

Standard Wording

There are risks with this, or any study. To give you the most complete information available, we have listed many *possible* risks. We do not want to alarm you, but we do want to make sure that you have had a chance to think about the risks carefully if you decide to try the study. Please be aware that there may be risks in participating in this study that we do not know about yet.

**DRUG EFFECTS**

***List risks of study drug******in descending order***

Ensure risks include the likelihood of occurrence (i.e. 4 out of 10 (or 40%) of people experienced…)

You may notice none, some, or all of these side effects. They may be mild, moderate, or severe. Many side effects disappear after treatment is stopped. The principal investigator may prescribe medications to ease the discomfort you may experience if any side effects occur. If any severe reaction to the study drug occurs, the principal investigator may interrupt or discontinue the study drug treatment.

The research team will be checking you closely to see if any of these side effects are occurring.

There may be side effects that are not yet known. You must tell the research team about any new symptoms you experience.

If incidental findings are noted, these will be reported to your family physician.

*Describe briefly additional discomforts associated with common tests/procedures such as blood draws, x-rays, etc… if these tests are not a part of the participants' normal clinical care. See examples below.*

*If applicable:* There is a possibility of pain, bruising, swelling or infection related to giving blood.

*If applicable:* The effects or discomforts of tests/procedures that are part of this study but are part of your normal clinical care will be reviewed by your [select one] family/treating doctor.

*If applicable* QUESTIONNAIRES: You may find the interviews and questionnaires you receive during the study upsetting or distressing. You may not like all of the questions that we ask. You do not have to answer those questions if you find them too distressing.

The study treatment may interfere with medications, both prescribed and over the counter, that you are currently taking. You should ask the research team if the study treatment could interfere with your medication(s) before consenting to be in this study. You should also consult with the research team before taking any new medications.

You will be told about any new information that might reasonably affect your willingness to continue to participate in this study as soon as the information becomes available to the research team.

*IMPORTANT: If your study includes a substudy that requires blood or tissue samples from participants but* ***NOT*** *for genetic research, please describe how you will take these* ***sample/ tissue, the safety and invasiveness of acquisition, as well as any additional risks associated with the sub-study.***

*IMPORTANT: If your study includes a substudy that requires blood or tissue samples from participants for genetic research, please include the following, additional wording at the end of the 'risks' section. Refer to* [*TCPS 2 Article 12.1, 12.2 and 12.3*](https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter12-chapitre12.html) *to fill the next paragraph.*

The kind of information we will look for in the name of your sub-study is not likely to tell you anything specific about your health. Even so, if someone allowed your genetic facts to become public knowledge, it could affect your ability to get or keep a job and/or your ability to get or keep various types of insurance, like life insurance. We think the chance of this ever happening to you is small.

To protect your information, we will not keep your name or other information that may identify you with the sample, only a code. Files that link your name to the code number will be held in a secure place. Although no one can guarantee confidentiality, using a code makes the chances much smaller that someone other than the research staff or other authorized groups or persons (discussed later in the consent form) will ever be able to link your name to your sample or to any test results.

Although we will not keep your name with the sample, the information provided with your sample may have other facts about you such as your race, ethnicity, and sex. These facts are important because they will help us learn if the factors that cause *insert disease/condition* that occurs or get worse are the same or different in males, females or other and in people of different racial or ethnic backgrounds. Thus, it is possible that research results could one day help people of the same race, ethnicity, or sex as you. However, through these kinds of studies, it is also possible that genetic traits might come to be associated with such a group. We do not know the effects that this knowledge could have on you or people like you.

*If applicable, required for genetic research:* If, as a result of your participation in this study, any new clinically important information about your health we obtain, we will give you the opportunity to decide whether you wish to be made aware of that information.

*When collecting and banking genetic material, address the associated ethical issues, including future contact of participants, families, communities and groups.*

# Are There Benefits Of Participating In This Study?

You may or may not benefit directly from participating in this study. However, possible benefits include describe possible benefits. NOTE: If a placebo-controlled study, you cannot promise ANY benefit from investigational product. Your participation may or may not help other people with condition in the future.

If there is likely to be no medical benefit to participation, then state: There are no medical benefits to you from taking part in this study.

# Are There Other Choices?

If you decide not to participate in this study, other treatment choices may be available. *State other treatment options.*

New treatments become available for this sort of condition at different times and in different parts of the world. Like many other hospitals, we do not feel it is helpful to test more than one experimental treatment for the same condition at the same time in the same person. This could be dangerous. So. you will not receive two experimental treatments at the same time.// So you will not undergo two experimental procedures at the same time.

You are free to seek other opinions or choices in other hospitals or cities if you wish.

# What Happens at the End of the Study?

*Briefly describe the participant's access to the study treatment when the study is completed, including any responsibility for paying for the treatment.*

*Provide details on the patient's ability to access the new drug upon study completion. If the drug will not be available, then state*: The study treatment will be provided to you only during this study and not after the study is over.

*Briefly describe the participant's access to the study results when the study is completed. Include whether the participant will be given a copy of the publication (if one is planned).*

# What Are My Responsibilities?

*Please include all applicable bullets, as well as additional bullets if there are other responsibilities that participants will have throughout the course of participation in your trial.*

As a study participant you will be expected to:

* Follow the directions of the research team;
* Report all the medications that you are taking or plan on taking;
* Report any changes in your health to the research team;
* Report any problem(s) that you experience that you think might be related to participating in the study;
* *List other participant responsibilities.*

# Can My Participation in this Study End Early?

Yes. The study sponsor, the Nova Scotia Health Research Ethics Board, Health Canada, The Food and Drug Administration (FDA), etc, and the principal investigator have the right to stop patient recruitment or cancel the study at any time.

The principal investigator may decide to remove you from this study without your consent for any of the following reasons:

* The treatment does not work for you;
* You do not follow the directions of the research team;
* You are experiencing side effects that are harmful to your health or well-being;
* There is new information that shows that being in this study is not in your best interest;
* You become pregnant or plan to come pregnant or plan to discontinue acceptable birth control.
* Other stopping rules applicable to this study (i.e. treatment efficacy, new risks, etc).

If you are withdrawn from this study, a member of the research team will discuss the reasons with you and plans will be made for your continued care outside of the study.

You can also decide to end your participation at any time. If you decide to withdraw from this study by providing notice to the research team, your decision will not affect your current or future medical treatment and healthcare. The agencies listed above, including the sponsor, might examine your health records with this study to ensure that the study is scientifically reliable and to report side effects you might have experienced with the study medication.

***Describe any procedures or tests you will ask the participant to follow or undergo if they withdraw from the research.***

You may be asked questions about your experience with the study treatment, and to cooperate with having laboratory tests and physical examinations considered necessary to stop your study involvement safely.

For all multi-visit studies: If you withdraw your consent, we will still use the information about you and type of sample/tissue that was/were collected before you left the study. No new information about you will be collected *and no further testing of your* type of sample/tissue *will be done* without your permission.

***If your study includes a sub-study for which blood or tissue samples will be required from participants for genetic research AND the samples will be stored for future research****, (****as per*** [***TCPS 2 Article 12.2 (b) and (e)***](https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter12-chapitre12.html) *please add the subsection heading "Can I Withdraw My Sample?" and one of the following, additional paragraphs to the end of this subsection. If the samples will not remain linked to participants at the end of the study, please use the first option. If the samples will remain linked to participants at the end of the trial, please use the second option.*

If you agree to have your \_\_\_\_\_\_ sample stored for future research, you can change your mind up until the end of the study, when we store the remaining samples. At that time, we will remove any information that may identify you. After we do so, we will not be able to withdraw your sample because we will not know which one is yours.

Of course you may request not to have further tests done or to participate in any additional study procedures at any time.

**OR**

If you agree to have your \_\_\_\_\_\_ sample stored, you may later decide that you want to withdraw it from storage. If you decide that you want to withdraw it from storage, you should contact one of the research team contacts listed in this consent form and tell them to have your sample discarded. Your sample will be discarded, but any data collected from testing your sample up until that point will remain part of the research.

# What Will Happen To My Sample After The Study Is Over?

***IMPORTANT: If this section is omitted from the consent form, please renumber all subsequent sections appropriately.***

***If the samples will NOT be stored for future research,*** *please insert the following paragraph:*

After this study is over, we will dispose of all the samples we collected as part of the \_\_\_\_\_\_\_ sub-study by burning them.

***If the samples may be used for future research****, please use the wording below (four paragraphs total) and select the appropriate option (****A.*** *or* ***B.****) for paragraph two.*

**Option 1**

After our study is over, we would like to keep any unused \_\_\_\_\_\_ samples leftover from the \_\_\_\_\_\_ sub-study and allow them to be used for future research related to \_\_\_\_\_\_. We will store the sample for \_\_\_\_ years in total, during which time they will be made available for various types of research.

**Option 2**

**A**. If you agree to have your sample stored for future research, we will store your samples with a code, and we will keep the file that links the code to your name confidential. We may share the samples with other researchers, but we will not give other researchers any information that would allow them to identify you. We will always know which samples belong to you, but other researchers will not. We want you to be aware that if the samples are sent to other countries, the same laws and regulations that we have here might not apply, and they may be used for purposes other than those that we outline in this consent form. They may even be used for things that are against your values and beliefs. Please keep this in mind when choosing whether or not to allow us to store your sample for future research. Please be aware that after you provide us with a \_\_\_\_\_sample, you have released your permission over how it may be used.

OR

**B**. If you agree to have your samples stored for future research, all information that might possibly identify you will be removed from your sample, and no one will ever be able to tell that it was yours. However, after this happens, you will not be able to withdraw your samples, as we won't be able to tell which sample was yours. We want you to be aware that if the samples are ever sent to other countries, the same laws and regulations that we have here might not apply, and they may be used for purposes other than those that we outline in this consent form. They may even be used for things that are against your values and beliefs. Please keep this in mind when choosing whether or not to allow us to store your sample for future research. Please be aware that after you provide us with a \_\_\_\_\_sample, you have released your permission over how it may be used.

**Option 3**

A research ethics board, like the one that helps protect you during this research project, will review and approve all future projects before any other researchers gain access to your sample.

**Option 4**

You can choose not to have your sample stored for future research and still be part of the \_\_\_\_\_\_\_ sub-study. You will have the chance to state whether or not you agree to have your sample stored for future research at the end of this consent form.

# What About New Information?

It is possible that new information may become available while you are in the study about side effects or a new treatment for your condition. You will be told about any other new information that might affect your health, welfare, or willingness to stay in the study and will be asked whether you wish to continue taking part in the study or not.

# Will It Cost Me Anything?

*State whether out-of-pocket expenses will be reimbursed with receipts provided. Indicate if there are any costs to participants. See examples of suggested text below. Note: The REB recommends that all study participants receive reimbursement for parking for visits above standard of care.*

Compensation

We will reimburse you for some study-related expenses such as parking, taxi, lunch. Please bring your receipts with you. *If applicable* You will receive payment *monthly, every six months, at each visit, etc…* throughout the study. *If applicable* If you decide to leave the study, you will receive a prorated payment for participating in the study.

*OR*

Participating in this study may result in added costs to you for <<parking, transportation, lunch, etc.

*If applicable* You will not have to pay for any study related treatments you take while participating in this study. You may need to pay for medications to treat any side effects you may experience as a result of participating in this study. Your private health care insurer may not pay for all of these added costs.

***THE RESEARCH RELATED INJURY SUBSECTION CANNOT CONTAIN ANY STATEMENTS THAT APPEAR TO LIMIT LIABILITY.***

Research Related Injury

If you become ill or injured as a direct result of participating in this study, necessary medical treatment will be available at no additional cost to you. Your signature on this form only indicates that you have understood to your satisfaction the information regarding your participation in the study and agree to participate in the study. In no way does this waive your legal rights nor release the principal investigator, the research team, the study sponsor or involved institutions from their legal and professional responsibilities.

*OR for Post-Marketing Studies*

The medicine being given to you in connection with this study has already received approval from the regulatory authorities in Canada. In the event that you suffer injury as a direct result of participating in this study, normal legal rules on compensation will apply. By signing this consent form you are in no way waiving your legal rights or releasing the principal investigator and sponsor from their legal and professional responsibilities.

***If your study includes a substudy for which blood or tissue samples will be required from participants for genetic research*** *(as per* [*TCPS Article 12.2 (c)*](http://www.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter12-chapitre12/#toc12-1c)*, please add ONE of the following, additional paragraphs to the end of the Compensation subsection, as appropriate to your study.*

If you decide to participate in the \_\_\_\_\_\_\_\_ substudy please note: The aim of our research is to improve the public health. Your \_\_\_\_\_\_\_ sample will never be used to develop a process or invention that will be sold or patented.

*OR*

If you decide to participate in the \_\_\_\_\_\_\_\_ substudy, please note: The aim of our research is to improve the public health. Sometimes, such research may result in findings or inventions that have value if they are made or sold. We may get a patent on these. We may also license these, which could give a company the sole right to make and sell products or offer testing based on the discovery. Some of the profits from this may be paid back to the researchers and the organizations doing this study, but you would not receive any financial benefits.

# What About My Privacy and Confidentiality?

*IMPORTANT: If your study does not involve an experimental drug, natural health product or device, please omit bullets 2, 3 & 4 from the list below which pertain to regulatory authorities.*

Protecting your privacy is an important part of this study and every effort to protect your privacy will be made. However, complete privacy cannot be guaranteed. For example, the principal investigator may be required by law to allow access to research records. Your family doctor will be told that you are taking part in this study.

If the results of this study are presented to the public, nobody will be able to tell that you were in the study.

If you decide to participate in this study, the research team will collect personal health information from you and your health record. The research team will collect and use only the information they need for this study and to judge the safety and usefulness of the study treatment.

"Personal health information" is health information about you that could identify you because it includes information such as your;

* Name,
* Address,
* Telephone number,
* Age or month/year of birth (MM/YY),
* Information from the study interviews and questionnaires;
* New and existing medical records, or
* The types, dates and results of various tests and procedures.

***If your study includes a substudy for which blood or tissue samples will be required from participants for genetic research*** *(as per* [TCPS 2 Article 12.2 and 12.3](https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter12-chapitre12.html#b)), *please include the following, additional paragraph.*

If you decide to participate in the name of substudy once we take your blood/tissue, sample, we will assign it a code number. We will separate your name and any other information that points to you from your sample. We will keep files that link your name to the code number in a locked file cabinet and office, away from your sample.

*Whether the sample/tissue will be linked to the participant,* ***the safeguards to protect the participant's privacy and confidentiality;*** Any of your (type of sample) that is sent outside of the hospital will have a code and your initials and will not contain your name or address, or any information that directly identifies you.

Access to Records

Other people may need to look at your personal health information to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines. These people might include:

* Sponsor Name, and its representatives and partner companies as per the title page of this consent form;
* The Nova Scotia Health Research Ethics Board (NS Health REB) and people working for or with the NSHealth REB because they oversee the ethical conduct of research studies within Nova Scotia Health;
* Representatives of Health Canada, who oversee the use of drugs, natural health products and medical devices in research in Canada, and other regulatory bodies such as the United States Food and Drug Administration (FDA);
* If applicable:When you sign this consent form you give us permission to collect information from the Department of Health and Wellness' SHARE Electronic Health Record which contains laboratory test results, Diagnostic Imaging as well as admissions, discharge and transfer records from across the province.

These people will view your study records at this institution, either remotely through secure access or in person, and will not take identifying information away with them.

Use of Your Study Information

Any study data about you sent outside of Nova Scotia Health will have a code and will not contain your name or address, or any information that directly identifies you.

De-identified study data may be transferred to:

* The sponsor and companies working for and with the sponsor and;
* Regulatory authorities within and outside Canada.

The sponsor and companies working for and with the sponsor will use the information collected about you during the study, only for scientific research and/or drug development purposes. Study data that is sent outside of Nova Scotia Health will be used for the research purposes explained in this consent form. If future use of the research data beyond the current study is anticipated, this should be explained. Provide participants with as much information as possible such as the type of research and any protections of participant confidentiality.

The research team and the other people listed above will keep the information they see or receive about you confidential, to the extent permitted by applicable laws. Even though the risk of identifying you from the study data is very small, it can never be completely eliminated.

The research team will keep any personal health information about you in a secure and confidential location for # of years and then destroy it according to NS Health policy. Your personal health information will not be shared with others without your permission.

After your part in the study ends, we may continue to review your health records for safety and data accuracy until the study is finished or you withdraw your consent.

The REB and people working for or with the REB may also contact you personally for quality assurance purposes.

Please be aware that once your identifiable or de-identified data is sent outside of Canada it may be accessed by regulatory authorities in other countries who may not have the same privacy laws as we do.

Your Access to Records

You have the right to access, review, and request changes to your study data. If applicable: Since the study is "blinded," you cannot see this information until the study ends. This prevents either you or your doctor from knowing which study treatment you received until the results are reported.

***Required for all studies subject to FDA's jurisdiction.***  A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>,. 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.

*Note: It is the responsibility of the researcher to consider and include as necessary other privacy issues such as photography, audio or video taping, and the inability to withdraw information in certain methods such as focus groups or re-coding for anonymity.*

# Declaration of Financial Interest

*IMPORTANT: If the principal investigator does have a vested financial interest in conducting the study, the last sentence of our requested wording should be amended to reflect this fact.*

The sponsor, funder is reimbursing the principal investigator and/or the principal investigator's institution to conduct this study. The amount of payment is sufficient to cover the costs of conducting the study.

*If the study is unfunded and the Principal Investigator has no vested financial interest in conducting the study, use the wording below (modify if the PI does have a vested financial interest)*.

This study is unfunded.  The PI has no vested financial interest in conducting this study.

# What About Questions or Problems?

NOTE: If you include the third and fourth paragraphs of our standard wording regarding contacting the specialist or physician on call, you will be required to confirm in your ethics submission that this person is (or these persons are) substantively aware of the study (e.g. – must be familiar with the study agent or device, what to do with regard to protocol errors, and must be familiar with the adverse and serious adverse event reporting procedures for the study).

For further information about the study you may call the principal investigator who is the person in charge of this study and/or any other research team member listed below.

The principal investigator is insert name of PI

Telephone: insert phone number

Your research coordinator is insert name of coordinator.

Telephone: insert phone number

If applicable: You may list the contact information for any additional person(s) the participant could contact for further information about the study (e.g. research assistant, etc.).

If you experience any symptoms, possible side effects or other medical problems, please let the principal investigator or research coordinator know as soon as possible.

If you can't reach the principal investigator or research coordinator after regular business hours, speak to the physician on call. The after hour's number is 902-XXX-XXXX**.**

This doctor may not be the one you usually see while in this study. Please call the principal investigator or research coordinator the next business day to tell them about the possible side effects or other medical problems you experienced.

# What Are My Rights?

You have the right to all information to help you decide whether or not to participate in this study. You also have the right to ask questions about this study and to have them answered to your satisfaction before you make any decision. You also have the right to ask questions and to receive answers throughout this study.  You have the right to withdraw your consent at any time.

If you have questions about your rights as a research participant and/or concerns or complaints about this research study, you can contact

1. The Nova Scotia Health Research Ethics Board Office
   * email: [ResearchEthics@nshealth.ca](mailto:ResearchEthics@nshealth.ca)
   * Phone: 902-222-9263
2. Patient Relations (CZ: see <http://www.nshealth.ca/contact-us> for appropriate zone contacts)
   * Email: [healthcareexperience@nshealth.ca](mailto:healthcareexperience@nshealth.ca)
   * Phone: 1-844-884-4177

-----------------------------------Page Break to the signature page---------------------------------

# Consent Form Signature Page

This page, documentation of informed consent, must begin on a new page.

*The NS Health REB advises that the PI sign the consent form within a two week period from the date the patient signed the consent form..*

I have reviewed all of the information in this consent form related to the study called:

Provide Full Study Title - same as the Protocol and REB application

I was given the opportunity to discuss this study. All my questions have were answered to my satisfaction.

I authorize access to my personal health information and research study data as explained in this form.

This signature on this consent form means that I agree to take part in this study. I understand that I am free to withdraw at any time without affecting my future care.

The box below is to be used for studies where there is collection/storage of optional samples (i.e. for a sub-study directly related to the main study), photography, audio recordings, etc. **CUSTOMIZE as required for your study.**

I agree to allow the collection, storage of my sample, photography, audio recordings as described in this consent form.

I do not agree to allow collection, storage of my sample, photography, as described in this consent form.

I agree to allow my type of sample(s) to be stored for future unknown research.

I do not agree to allow my type of sample(s) to be stored for future unknown research.

E-messaging (email and texting) can be used by a member or members of the research team to communicate with you while you are in this study. All communication done with you will be done through an NS Health email account or text by a phone issued to a research member through NS Health. All efforts are made to keep information sent or received private, but it is possible other people may be able to see, read, and change messages sent to or from NS Health.

I give my permission to be contacted by a member or members of the research team from an NS Health email account or an NS Health cell phone by research staff to communicate during this study. \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (initials and date).

Email YES  NO

Text message YES  NO

I do not wish to be contacted by email or text message, unless I otherwise give permission at another time during this study \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (initial and date).

Not applicable.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_**

Signature of Participant Name (Printed) Year Month Day\*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_**

Signature of Person Conducting Name (Printed) Year Month Day\*

Consent Discussion

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_**

Signature of Principal Investigator Name (Printed) Year Month Day\*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_**

Signature of Participant's Name (Printed) Year Month Day\*

Substitute Decision Maker

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_**

Signature of Impartial Witness Name (Printed) Year Month Day\*

If you answered yes to question 6.14 on the EAF: If a participant is unable to read, an impartial witness must be present during the entire informed consent discussion and must sign the consent form as described in ICH GCP 4.8.9. This witness cannot be a member of the study team. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently[seemed to be] understood by, the subject or the subject's legally acceptable representative, and that informed consent was freely given by the subject or the subject's legally acceptable representative (ICH GCP 4.8.9).

If the consent discussion was in a language other than English, please indicate:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Language

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_**

Signature of Translator Name (Printed) Year Month Day\*

***\*Note: Please fill in the dates personally***

**I will be given a signed copy of this consent form.**

***Thank you for your time and patience!***

**Example STUDY PLAN [Modify as applicable]**

<< Another way to find out what will happen during this study is to read the study plan below. Start reading at the top and read down the list, following the arrows. >>

[Please modify as applicable].

Start Here

Informed Consent

Screening

Randomization

Study Drug A

1 year

Placebo Group

1 year

Study Drug B

1 year

1 year post treatment follow up

1 year post treatment follow up

1 year post treatment follow up

**Example Schedule of Assessments**

This type of table can help illustrate what is involved in the study. List what will happen at each visit. Ensure the entire table fits into one page and is not separated into two pages.

Boxes marked with an X show what will happen at each visit

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Visit | Screening | Baseline | Visit 1  [select one] Week/  Month X | Visit 2  [select one]  Week/  Month X | Visit 3 | Visit 4 | Visit 5 | End of study visit |
| Time | 2 hours | 90 minutes | 30 minutes | 1 hour |  |  |  |  |
| Informed consent | X |  |  |  |  |  |  |  |
| Medical history | X |  |  |  |  |  |  |  |
| Height and weight | X |  |  |  |  |  |  |  |
| Blood test | X | X |  |  |  |  |  |  |
| Pregnancy test (if applicable) | X | X |  |  |  |  |  |  |
| Physical exam |  | X |  |  |  |  |  |  |
| Questionnaire |  | X |  |  |  |  |  |  |
| Food diary |  | X |  |  |  |  |  |  |
| Study Drug/Placebo |  | X |  |  |  |  |  |  |