UHN REB Consent Form Guidance Document

Blue text = Guidance and/or instructions
Black text = Recommended wording

1. **Document Title:**
   Add particular subgroups within a study if applicable. This enables everyone to differentiate between consent forms and groups within a study. (e.g. control group, biomarker sample collection, genetic sample collection).

2. **Study Title:**
   Enter the full title of study, exactly as it appears on the Protocol. Add protocol number if applicable. Should the title be complicated, a title in simplified lay terms could be included after the full title of the study.

3. **Principal Investigator:**
   Enter the name with title and telephone number of the Principal Investigator. Indicate "Dr." only for doctors licensed to practice in Canada; indicate "Nurse" only for nurses licensed to practice in Canada. All other Investigators should be referred by their credentials and, if applicable, country of practice. (E.g. "Dr. Tom Smith," "Ms. Jane Smith, Nurse Practitioner, "George Brown. Ph.D." "George Brown, Nurse Practitioner, (New Zealand)"

4. **Co-Investigators:**
   
   Listing Co-Investigators is discouraged but, for studies involving expertise from different departments (multimodal studies), should be considered.
   If you choose to enter the names and titles of Co-Investigators keep in mind that at any point there is a change in a co-investigator, the consent form will require revision, review and approval by the REB.

5. **Contact Information:**
   Provide a 24-hour phone number for clinical trials. This may be a pager number (in this case change the heading to "Pager number".) If no other direct 24-hour contact number is available, enter the locating number and direct participants to the relevant **staff** physician on call (e.g. anesthesiologist, cardiologist etc). Clearly provide instructions to contact physician on call (e.g. "This is a general locating number. Ask for the cardiologist on call"

   
   Do not include any mailing address unless required by the study design.

6. **Sponsor:**
   Enter the full name of all sponsor(s) as documented on the protocol and/or application form, including funding sources and drug suppliers. UHN should not be indicated as a sponsor.

7. **Introduction:**
   Enter the language as per the UHN Consent Form Template.

8. **Background/Purpose:**

The following information **must** be in the consent form, preferably in this section:

8.1. The background of the study such as experience to date, data from other studies that led to the development of this study.

8.2. The purpose of the study

The purpose of this research study is [insert purpose/significance of conducting the study. Insert an explanation of the problems or limitations of the current standard of care that would justify carrying out the research study (e.g. high pill burden, limited efficacy, numerous side effects, and serious side effects etc.…). The limitations are not restricted to the above. These are some examples and guidance for you.]

8.3. The reason for participation

You are being asked to participate because [Insert the main reason(s) the individual is being asked to participate (e.g. you have kidney disease, you are a healthy individual with no history of kidney disease, you will be having a biopsy, you will be having a CABG procedure, etc.).

Do not include an extensive list of inclusion/exclusion criteria.

8.4. The usual/standard of care treatment

The usual treatment for your disease is [insert standard of care and how it will be altered]

8.5. For each investigational intervention provide a statement indicating it is not standard of care or not approved followed by a statement stating it is approved for use in this research study.

The [insert intervention] is experimental. Experimental means Health Canada has not approved the sale or use of [insert the intervention name/procedure or description as applicable] but they have approved its use in this research study. Indicate if there are other approved [interventions] being used.

Do not include: “This study has been approved by the research ethics committee….” since this may appear to offer a guarantee of safety. This is to conform to Health Canada guidelines for study consent forms. (See: http://www.hc-sc.gc.ca/sr-sr/advice-avis/reb-cer/consent/index-eng.php , section: “Consent Form Don’ts”)

8.6. The number of people to participate.

Up to [#] people will participate in this study with [#] at UHN and it will take [#] year(s) complete.

8.7. The length of the study.

8.8. The number of people exposed to the experimental intervention and brief experience to date.
[##] people have received this [name of intervention] and was well tolerated.

9. **Study Design:**
Describe the design of the study. Insert one of the applicable study designs below:

9.1. Randomized Double-Blind:
This is a randomized double blinded study. If you decide to participate you will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor your doctor can choose what group you will be in. You will have a [insert randomization probability e.g., 50/50; 50%; 1 in 3] chance of being placed in [either]/[any] group. Neither you nor your doctor will know which group you are in. In an emergency, if the study [intervention] needs to be identified the doctor can get this information.

9.2. Randomized Single-Blind:
This is a randomized blinded study. This means that you will not be told whether you are on [insert the intervention] or on [insert the intervention] until the study is finished. You will receive either [the intervention] or [intervention]. If you decide to participate you will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor your doctor can choose what group you will be in. You will have a [insert randomization probability e.g., 50/50; 50%; 1 in 3] chance of being placed in [either]/[any] group. You will not know if you are taking [insert intervention]. In an emergency, if the study [insert intervention] needs to be identified the doctor can get this information.

9.3. Open-label:
All participants will receive (insert study intervention).

9.4. Phase 1:
The purpose of this study is to test the safety of a new drug *[insert intervention]* to see what effects it has on humans and [*insert disease/condition]*.
or
The purpose of this study is to find the highest dose of a new drug *[insert intervention]* that can be given without causing very severe side effects that are not tolerable. This is done by starting at a dose lower than the one that does not cause side effects in animals. Participants are given *[insert intervention]* and are watched very closely to see what side effects they have and to make sure the side effects are not severe. If the side effects are not severe, then more participants are asked to

join the study and are given a higher dose of *[insert intervention]*. Participants joining the study later on will get higher doses of *[insert intervention]* than participants who join earlier. This will continue until a dose is found that causes severe but temporary side effects. Doses higher than that will not be given. Your study doctor will tell you at which dose level you will start the study drug.

9.5. Extension Study:
You are near completion of the main study in which you received (insert intervention) over (list time period - e.g. ## weeks). In this extension study, all participants will receive the study drug. List relevant additional information such as: If you were on placebo, you will now receive the active study drug. If you were on the active study drug, you will continue on your previous dose.

9.6 Study Employing placebo:
Explain why using placebo is necessary, e.g. A placebo is given in this study to reduce the chances of believing that disease is getting better because of receiving a new drug. Really, we don't know if the new drug or no drug (with or without the standard drug) is better than the other so we are doing this study to try and find that out.

Do not define placebo as: “dummy tablets”. Instead use a description like: “Placebo – a pill/procedure that looks real but actually contains no active ingredients.”

10. **Procedures:**

10.1. List the different types of visits to take place such as screening, baseline, visit 1, end of study visit, early termination visit etc. and what is required of the participant at each of these visits.

10.2. Ensure to clarify research related procedures and standard of care procedures. The consent should focus on the research related procedures and discuss standard of care where necessary.

10.3. Quantify the amount of body fluids/tissue to be taken at each visit. Examples are: mL, tsp, tubes, pathology slides etc. If quantifying in spoons or tubes, indicate in mL as well.

10.4. Insert # of visits. Example: There will be ## of visits during your participation in this study.

10.5. Present procedures in bullet format

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

- Medical History
- Physical Exam
- Blood draw

- Catheter Blood draw
- Pregnancy Test - If you are a woman and can have children, you will need to have a pregnancy test before starting the study drug to be sure that you are not pregnant. If you are pregnant, you cannot participate in this study. Specify if urine or blood or both will be taken and quantity
- X-ray – Specify type
- MRI - Use of magnetic waves to take pictures of the inside of your body. You will have to lie still in a MR machine but will be able to speak to someone at all times.
- MRI with gadolinium contrast - Use of magnetic waves to take pictures of the inside of your body. You will have to lie still in a MR machine but will be able to speak to someone at all times. Prior to the MR scan you will have a gadolinium contrast injection via IV (intravenous catheter) to evaluate blood vessels.
- ECG - An electrocardiogram is a test that measures the electrical activity of the heart. Patches attached by wires to a machine will be put on your chest so that the machine can record the pattern of your heart beats.
- Echocardiogram **–** A test that uses sound waves to create a moving picture of the heart to measure how well your heart is functioning. The picture is much more detailed that a regular x-ray picture and does not involve any radiation exposure. An instrument that sends high frequency sound waves is placed on your ribs near the breast bone directed toward your heart.
- MUGA Scan - A radioactive tracer is injected via IV (intravenous catheter) which attached to blood cells. Then an instrument is used to see inside your heart.
- CT scan **-** an x-ray machine that makes computerized pictures of the inside of your body
- CT scan with contrast - A dye will be injected via a needle into your body. An x-ray machine that makes computerized pictures of the inside of your body.
- Dexa Scan - A bone mineral density scan is a specialized x-ray test that measures the amount of calcium in the spine and hip. It is a non-invasive procedure and it takes about 15 - 30 minutes.
- Blood transfusion
- Skin Photography - Describe exactly what will be photographed
- HIV/Hep B/C Screen - Include the following statement: “Positive test results are reportable to local health authorities”.
- Videography (e.g. Parkinson’s symptoms) **-** Describe exactly what will be videotaped
- Questionnaires

- A pulmonary function test - (a group of tests that measure how well your lungs take in and let out air and how well they move oxygen into your blood) will be performed.
- Biomarker (biological flags used to measure disease progress or drug effect) - describe what will be done (e.g. blood draw)
- Mandatory tissue sampling - Describe the type, the method, the amount, and any conditions that may apply
- Optional tissue/body fluid/other sampling (**provide a separate consent form for each**): future banking, pharmacogenetic (genetic characteristics in an individual used to measure disease progress or drug effect) or pharmacogenomic (genetic characteristics in a population/group used to measure disease progress or drug effect).

10.7. Insert a table with a summary of procedures including approximate time commitment (as applicable based on the protocol). See below example:

Summary of Tests and Procedures

Visit	**Tests and Procedures**
Screening	Routine blood tests, complete questionnaire, sample collection.
Visit 1 *approx visit length*	Begin study drug
Visit 2 *approx visit length*	Blood tests
Visit 3 *approx visit length*	Blood tests
Visit 4 *approx visit length*	Blood tests
Visit 5 *approx visit length*	Blood tests and exams. 2nd chest x-ray for research purposes

10.8. You will be in this research study for ## days/weeks/months/years.

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

11. Voluntary Participation:

11.1. Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. You may leave the study at any time without affecting your [care/employment status/academic

standing - choose only those that are applicable]. We will give you new information that is learned during the study that might affect your decision to stay in the study.

11.2. If applicable, insert: You may refuse to answer any question you do not want to answer, or not answer an interview question by saying "pass".

11.3. For studies involving genetic tests and if applicable to the study participant population, insert the following:
If you are a First Nations or an indigenous person who has contact with spiritual 'Elders', you may want to talk to them before you make a decision about this research study. Elders may have concerns about some genetic procedures.

12. **Withdrawal from Study:**

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

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

If the sponsor **will allow** the participant **to have their data withdrawn** when the participant withdraws from the study, insert the following:
Data:
If you decide to withdraw from the study, you have the right to request withdrawal of information collected about you. Let your study doctor know.

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

If the study site **will continue to use the participants data** after they have withdrawn from the study:
Data:
If you decide to withdraw from the study, the information that was collected before you leave the study will still be used in order to help answer the research question. No new information will be collected without your permission.

Studies involving tissue/blood/body fluids:
If you decide to withdraw from the study, you have the right to request withdrawal of your [insert types of samples as applicable to study – e.g. blood, tissue, etc]. Let your study doctor know. However, after these records linking your identity to your sample are destroyed, it will no longer be possible for [sponsor] to discard

your sample if you withdraw your consent. [sponsor] will keep and use any research results that we obtain prior to your withdrawal of consent.

Should the link to the samples be destroyed, indicate so and state for how long samples could be withdrawn and add After these records linking your identity to your sample are destroyed, it will no longer be possible for [sponsor] to discard your sample if you withdraw your consent.

The participant should not be contacting the Sponsor directly to withdraw. The participant's identifiable information should remain with the study site. The participant should only contact their study team to withdraw.

A participants request to withdraw from the study cannot always be written. There are cases where participants discontinue visits after verbally telling their study doctor, participants are lost to follow up and participants cannot write in English. Therefore, as a requirement, language in this section must include written or verbal withdrawal and if the sponsor requires a written notification of withdrawal, the study doctor may provide written notification to the sponsor.

13. **Risks:**

13.1. Include a list of all study related side effects.

13.2. Include risk of receiving placebo/delayed surgery/ delayed/withdrawn standard of care treatment if applicable

13.3. Address psychological risks such as anxiety, distress, embarrassment, or feelings of sadness that may arise from questionnaires and interviews about sensitive issues (e.g. mental health, sexuality).

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

13.5. Use plain language to describe or explain. Examples of unacceptable language in the risks include: punctate subepithelial, corneal opacity, low lymphocytes, hypertension, myocardial infarction, edema etc.

13.6. Explain the significance of a side effect if it is not obvious.
Example: Low white blood cells may decrease your ability to fight infection or may increase your ability to get a new infection.

13.7. List frequency and severity of side effects. Side effects that have not been clearly linked to the study drug should also be included. For example: Increases and decreases in blood pressure have been noted in some patients receiving the study drug but it is not clear whether these effects are truly related to the study drug.

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

Very likely [Very Common] (*50 to100%)*:

- *[…]*

Likely [Common] (*20 to 49%*):

- *[…]*

Less Common (*1 to 19%*):

- *[…]*

Rare (less than 1%):

- […]

Rare but Serious (less than 1%):

- […]

13.8. **Studies in the early phase of development:**
The investigational [name of intervention] is in an early phase of development and so the side-effects in humans are unknown at this time. Animal studies to date show *[list as per Investigator Brochure].* There may be additional risks and side-effects that are currently unforeseen and, therefore, not listed in this consent form.

When limited numbers of individuals have been exposed to the intervention (less than 100), and the risks cannot accurately be quantified, the following language should be included:

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

- n experienced headaches
- n experienced diarrhea

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

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

Risks of [Intervention]:
Insert all relevant risks.

Risks of Placebo:
You may be given placebo, or inactive substance, during the study. If you receive placebo, your condition may go untreated and your symptoms may worsen as a result.

Risks of X-ray - Exposes you to doses of radiation.

Risks of MRI - Except for the noise, it is painless and safe. If you have any metal in your body, you will need to tell the staff. There is no radiation. Some people may feel a little 'closed-in' the MR machine, but you will be able to speak with someone at all times and can stop the test at any time.

Risks of MRI with Gadolinium Contrast - Except for the noise, it is painless and safe. If you have any metal in your body, you will need to tell the staff. There is no radiation. Some people may feel a little 'closed-in' the MR machine, but you will be able to speak with someone at all times and can stop the test at any time.

Gadolinium is a contrast agent used in MR imaging that helps to increase the visibility of abnormal tissues and see blood vessels. It has been in routine use for over 20 years. Gadolinium contrast is not safe to use in people who have kidney problems. If you have had a problem with your kidneys, please inform us of this problem before proceeding any further. There is a small risk of allergic reaction with gadolinium that can include symptoms of itchiness or rash. Rarely, a serious reaction may develop involving your kidneys leading to hardened skin lesions all over your body and stiffening of your joints. You must seek medical attention if you develop any symptoms of allergic reaction.

Risks of ECG - This test is painless and you should not feel anything while the ECG is done. Since the ECG machine will be connected to your body by sticky patches, like bandages, these may cause your skin to become mildly irritated.

Risks of Echocardiogram - No known risks

Risks of MUGA Scan - Exposes you to low levels of radiation with the radioactive tracer. The radioactive tracer is eliminated in approximately 24 hours.

Risks of CT Scan - Exposes you to moderate levels of radiation. One CT scan equals 70 chest x-rays.

Risks of CT Scan with Contrast - Exposes you to moderate levels of radiation. One CT scan equals 70 chest x-rays. You may develop an allergic reaction to the dye used for the CT Scan.

Risks of Dexa Scan - Exposes you to low levels of radiation approximately 1/5 to 1/2 (20-50%) that of a chest x-ray.

Risks of Blood Transfusion - Even though you'll be given blood that matches your blood type, it's still possible that you could have an allergic reaction to parts of the

transfused blood. Signs and symptoms are usually limited to hives and itching. It may also include a fever which could be an early sign of a reaction. These types of transfusion reactions are usually treated with antihistamines and are seldom serious. Rarely, an allergic reaction includes difficulty breathing, low blood pressure, chills, anxiety, rapid heartbeat and nausea. The nurses administering the transfusion are trained to help you.

All of our blood for transfusion comes from the [Canadian Blood Services]. They have taken great care to make sure the blood you are given is safe. However, there is a very small risk of getting an infectious disease from a blood transfusion. It is also possible that new disease will be found in donor blood in the future.

Some risks of transfusion are:

- Allergic Reactions: Those are usually mild and easily treated.
- Fever: Usually seen in patients who have been transfused before or who have ever been pregnant.
- Hemolytic Reactions: These reactions destroy the transfused red blood cells. These reactions are rare but can be serious and cause bleeding and kidney failure.
- Infection: All blood donors are carefully questioned to see if they might have infected blood. And all blood is carefully tested. But it is impossible to completely take away the risk of infectious disease being in donor blood.

Risks of infection include:
HIV: 1 in 4,000,000
Hepatitis B: 1 in 31,000
Hepatitis C: 1 in 3,000,000
HTLVL 1 in 2,000,000
Creutzfeldt-Jakob Disease (Mad Cow Disease) has been shown to be transmissible in blood products. No test exists for this, but various measures have been taken to reduce risks**.** There may also be

Risks of Blood Draw/Catheter Blood Draw - There is a possibility of pain, bruising, swelling, or infection related to giving blood.

Risks of Skin Photography - If applicable, insert: Risk of breach of confidentiality

Risks of Videography - If applicable, insert: Risk of breach of confidentiality.

Risks of Questionnaires - Sensitive questions?

Risks of Mandatory tissue sampling - Risk depends on the method (e.g. aspirate, punch biopsy, incision biopsy etc. – therefore list applicable risks).

Risks of Archival Tumor Tissue Collection

There are no physical risks to you in releasing archived tumor samples for the purpose of this study since the tissue has already been obtained by a previous biopsy/surgical procedure. However, it is possible that if your tumor tissue is released for this study, there will be insufficient tumor tissue for any possible future testing that requires tumor tissue.

Risks and Information Related to Pregnancy – List known risks in.
The [intervention] used in this study [might be/are known to be] harmful to an unborn baby or sperm. Women should not breastfeed while on this study because the drugs used in this study might be present in breast milk and could be harmful to a baby.

You must not become pregnant or father a baby while receiving the study [intervention and for ## months after the last dose of the intervention] because the drugs [and/or procedures] used in this study might be harmful to an unborn baby. Your study doctor will discuss methods with you to ensure that you do not become pregnant or father a baby during the study. If you are a man, you should not donate sperm while receiving the study [intervention and for ## months after the last dose of the intervention]. If you do become pregnant during the study or if you father a baby during the study you should immediately notify your study doctor.

The sponsor would like your permission to follow your pregnancy to gather information on the outcome of your pregnancy and/or the health of the baby. Should pregnancy occur, and you agree to be followed, you will be asked to sign a separate consent form.

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

If applicable, insert:
Some of the [intervention(s)] used in the study may make you unable to have children in the future. Your study doctor will discuss this with you.

If applicable, insert: Known interactions or contraindications with specific contraception methods.

Some sponsors follow pregnancy as part of standards for safety reporting. Pregnant participants must be consented to be followed whether it is for safety reporting as, once they become pregnant, they are withdrawn from the study and all rights to collect information have been lost. Therefore, they should be re-consented using a separate consent form to give permission for their pregnancy to be followed.

Therefore, the UHN REB approved consent form **must** include the following statement:
The sponsor would like your permission to follow your pregnancy until term to gather information on the pregnancy and the health of the infant. Should pregnancy occur, and you agree to be followed, you will be asked to sign a separate consent form.

14. **Benefits:**

You may not receive direct benefit from being in this study. Information learned from this study may help [insert the disease/reason for the study] in the future.

15. **Reminders and Responsibilities:**

List participant responsibilities and other important instructions participants should keep in mind during the study. The following is sample wording including examples:

It is important to remember the following things during this study:

- You should not eat for 12 hours before visits.
- Do not take medications before visits.
- Do not eat grapefruit or drink grapefruit juice during this study.
- Ask your study team about anything that worries you.
- Tell study staff anything about your health that has changed.
- Return study medication/diaries.
- Tell your study team if you change your mind about being in this study.

 Include only those relevant to your protocol.

16. **Alternatives to Being in the Study:**

You do not have to join this study to receive treatment for your condition.
The following are approved medications/interventions for your condition:

List the approved interventions currently available for the study population.

17. **Confidentiality:**

Personal Health Information

If you agree to join this study, the study doctor and his/her study team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could identify you and includes your:

- name,
- address,
- date of birth,
- new or existing medical records, that includes types, dates and results of
- medical tests or procedures.

→ If your study is a Health Canada regulated study, insert the following:
The study doctor will keep any personal health information about you in a secure and confidential location for a minimum of 25 years as required. A list linking your study number with your name will be kept by the study doctor in a secure place, separate from your study file.

→ If your study is **NOT** a Health Canada regulated study, insert the following:
The study doctor will keep any personal health information about you in a secure and confidential location for a minimum of 10 years. A list linking your study

number with your name will be kept by the study doctor in a secure place, separate from your study file.

Only the study team or the people or groups listed below will be allowed to look at your records. Your participation in this study also may be recorded in your medical record at this hospital. This is for clinical safety purposes.

The following people may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study is following proper laws and guidelines:

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

- The study sponsor or its representatives/partner companies.
- Representatives of the University Health Network (UHN) including the UHN Research Ethics Board

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

- Representatives of Health Canada or other regulatory bodies (groups of people who oversee research studies) outside of Canada, such as the United States Food and Drug Administration.

Study Information that Does Not Identify You

Some study information will be sent outside of the hospital to the Sponsor. Any information about you that is sent out of the hospital will have a code and will not show your name or address, or any information that directly identifies you.

The Sponsor may use the study information and share it with its partner companies or with national and international regulatory agencies to help answer the study question, to get approval to sell [insert intervention], to develop future studies on this product or for research related to this study.

All information collected during this study, including your personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law.

You will not be named in any reports, publications, or presentations that may come from this study.

→ Insert if applicable:

Your health information from this research project will be sent to other countries but your identifiers will be removed. They will not be able to identify you.

18. **Costs:**

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

18.1. Include whether participants will incur any expenses as a result of their participation in the study. Include any remuneration, gifts in-kind, vouchers, etc

to participants and how reimbursement will be pro-rated if participants withdraw early from study.

18.2. Indicate whether the cost of standard of care interventions or interventions given in combination are included or whether the participant will have to pay for them. List interventions they will have to pay for.

19. **Rights as a Participant:**

This section shall not have qualifiers that suggest that a patient's rights to care could potentially be compromised in the event of study related injury and should only include the standard UHN wording.

Examples of **Unacceptable** Sponsor Wording:

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

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

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

- The word "protocol" is not meaningful to patients because patients do not have access to the protocol. Therefore, it is not appropriate to refer to it.
- The above statements suggest a participants rights to care could potentially be compromised in the event of study related injury.
- Protocol Deviations may occur during a study. Since deviations are procedures that occur "NOT according to the protocol" the Sponsor is suggesting that patients are held responsible for actions that may be outside of the control of the patient. Therefore, in the event of a protocol deviation resulting in a negative consequence or harm to the patient, someone (not the patient) needs to be held responsible. (That someone would be the Sponsor or the Site - this must be dealt with at the contract level, not the consent form level).
- Due to the nature of harm, the study doctor cannot always be notified immediately.

20. **Conflict of Interest:**

For sponsored studies:

[Insert name of company], the sponsor of this study, will reimburse the hospital and researcher for the costs of doing this study. All of these people have an interest in

completing this study. Their interests should not influence your decision to participate in this study.

For internally funded studies:
Researchers have an interest in completing this study. Their interests should not influence your decision to participate in this study.

Include all information about any real or perceived conflicts of interest (e.g.: past consultation, past service on advisory board, financial, stocks etc). If the PI or CO-Is have specific conflicts of interest, include them in the below wording (e.g. Dr. S has served on the advisory board at company x.)

21. **Commercialization:**
[Enter sponsor's name] and/or others intend to claim sole ownership of any research results consistent with this consent. You will not receive any financial benefit that might come from the research.

22. **Questions About the Study**
If you have any questions, concerns or would like to speak to the study team for any reason, please call: [Principal Investigator] at [Phone] or Study Coordinator at [Phone]. The 24-hour contact number can be repeated here if determined to be needed for the study (e.g. blinded study).

Specific study coordinator names are discouraged to prevent frequent change in consent form due to personnel revisions. You are encouraged to provide other forms of contact information such as contact cards.

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (UHN REB) or the Research Ethics office number at 416-581-7849. The REB is a group of people who oversee the ethical conduct of research studies. The UHN REB is not part of the study team. Everything that you discuss will be kept confidential.

23. **Consent:**
Include participant consent section as per the Consent Form Template.

Do not repeat elements of the consent form (e.g. "you agree to follow the study doctor's instructions, you understand that you may withdraw at anytime etc.).

If you are including people who do not understand English, insert the following:

Was the participant assisted during the consent process? ☐ **YES** ☐ **NO**

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

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

Print Name of Translator	Signature	Date

Language

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

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

Print Name of Witness	Signature	Date

Relationship to Participant

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

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

Name of Substitute Decision Maker	Signature	Date

Relationship to Participant

Other Sections that must be included if applicable:

24. **Communication with Primary Care or Treating Doctor:**
We would like your permission to contact your family physician to obtain additional medical information or to let them know you are participating in this research study.

Please check off the appropriate box below indicating your choice to allow us to communicate with your physician or primary care provider.

The study doctor may tell my regular family doctor about my being in this study:
❒ YES ❒ NO

25. **Data Safety Monitoring:**
A Data Safety Monitoring board is a group of experts who will be reviewing the data throughout this research study to see if there are unexpected or more serious side effects than described in this form. The experts in the group are/are not (choose one that is applicable) employees of the sponsor, the study doctor or the hospital/clinic.

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

Other Requirements:

27. Do not include participant ID #, study #, participant phone #, or participant email address on the consent form. There should only be one log that links the ID# and demographic information. This should be separate from other identifying information and clinical information. **The only identifier accepted by the UHN REB on the consent form is the participant's name and signature.**

28. Do not include "patient initials" line on any page of the consent form as it does not verify that the potential participant has read each page and line. The signature at the end attests that the participant was explained everything regarding the study and agrees to participate as per the "consent process" not just by reading the consent form.

29. Do not use "subjects" as it is derogatory. Instead use "participants" throughout the consent form.

30. Do not refer to the consent form as "confidential". While this document must be treated confidentially by the study staff, the study participants have rights to discuss the study and consent with other people. The word "confidential" on the consent form may give participants the wrong impression.

31. Use plain language and define medical terms. Please refer to article 3.2 of the TCSP2.

32. Write the consent form for easy readability

33. PROOFREAD before submitting to REB. The REB will NOT correct spelling or grammar.