**PARTICIPANT INFORMATION AND CONSENT**
TITLE OF CONSENT

**STUDY TITLE:**

**Sponsor:**

**Study Number:**

**PRINCIPAL INVESTIGATOR:**
**CO-INVESTIGATORS:**

## Invitation to Participate:

You are invited to participate in a clinical research study of an investigational drug/(device/procedure), (Sponsor Name/Granting Agency). Before agreeing to take part in this research study it is important that you read the information in this consent form. It includes details we think you need to know in order to decide if you wish to take part in the study. This document provides you with information about the research study to help you make an informed decision about your participation. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish. Participation in any research study is voluntary. If you chose not to participate, you and your family will continue to have access to customary care at Humber River Hospital. If you decide to participate in this study you can change your mind without giving a reason, and you may withdraw from the study at any time

## Investigator Disclosure/Health Care Provider:

Your health care provider may be an investigator of this research protocol, and as an investigator, is interested both in your clinical welfare and in the conduct of this study. Before entering, or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way associated with this project. Before you can make an informed decision whether to participate, you need to understand the possible risks and benefits that are associated with this study.

You are not under any obligation to participate in any research project offered by your doctor. The study doctor and/or institution is/are paid to conduct this research study by (Sponsor Name/Granting Agency).

## Purpose of this research study

A comprehensible statement of the research purpose. .

## Study Design/Procedures/Treatments

Indicate the reason why the potential participant is being approached.

Describes the stage of disease and usual treatments, and if applicable include an explanation that the Participant may not receive the usual treatment if they participate in a research study.

States which drug(s), treatment(s) or delivery technique(s) has or has not been approved for this indication by Health Canada (for Division 5 CTA trials) although it has been allowed for use in this research study.

## What will happen during the study

Describes treatment by treatment group

In the case of randomized trials, the probability of assignment to each option. Probability for random assignment to each treatment.

Describes trial treatment, tests, and procedures to be followed, including invasive procedures

Identifies any procedures/treatment/aspects of the study that are experimental and what is standard of care.

## How many people will take part in the study

Approximate number of participants involved in the research study

## What are the responsibilities of study Participant?

Describes what happens at each visit, frequency of visits, all study treatments and procedures using lay language and list chronologically, expected duration of participation in the research study. Any medical terms should be defined and fully explained.

Outline the time commitment for each study visit. Overview and in chart form for complicated studies.

List the frequency of the procedures etc and where they will be performed

Describes participant's responsibilities.

Expected duration of the participant's participation in the research study.

**For collection of specimens or human tissue:**
It is strongly recommended that a separate consent form be used for future uses of data or samples, unless it is a mandatory part of the main study.

If tissue/blood banking is required, the consent must clearly state the specific, defined reasons the banking is required, and the defined, finite duration for which the samples will be stored.

For the purpose of obtaining free and informed consent, researchers who seek to collect human tissue for research shall, as a minimum, provide potential donors or authorized third parties information about:

The purpose of the research (for future research, for the current study only etc.)

If future use of the research data beyond the current study is anticipated, this should be explained (for example, subsequent use of videos, DNA banking, and creation of a permanent cell line).
The purpose of future research on this data should be explained to ensure that specific consent from the participant is obtained.

Set out options for the participant regarding the possible uses of samples ensuring that the consent you request is as specific as possible. Consent which is not sufficiently specific is not considered to be valid consent. Thus, the goal is to ensure that consent obtained for studies in the future on collected samples will satisfy the research ethics board reviewing the future study.

The type and amount of tissue to be taken, as well as the location where the tissue is to be taken;

The manner in which tissue will be taken, the safety and invasiveness of acquisition, and the duration and conditions for preservation

The potential uses for tissue including any commercial uses;

The safeguards to protect the individual's privacy and confidentiality;

Identifying information attached to specific tissue, and its potential traceability;

How and where will the samples be stored.

Will the participant receive results of the testing

Will the sample be linked to the participant

Length of storage

If Participant withdraws consent, what happens to the sample

How will they be destroyed/disposed of

Will the tissue samples be returned to the site

## **Contraception and Reproductive Risks**

If participants of childbearing potential, the reasonable foreseeable risks to an embryo, fetus or nursing infant

Both men and women must use adequate birth control (list all allowed methods i.e. birth control pills, using barrier methods such as condoms, vaginal diaphragm with spermicidal jelly, or sponge) while participating in this study as it is unknown what the affect of study medications will have on the fetus or sperm. Should you become pregnant during the study, you will be required to discontinue the study.

Clause for Male Participants
***For male Participants who are participating in this research study:*** *You need to understand that while you are participating in this research study, there could be potential risks to an embryo or fetus, which are currently unknown, unforeseen or unanticipated. While taking this study drug you or your partner need to use effective means of birth control: oral contraceptive pills or an IUD, diaphragm and condom with spermicidal gel or foam (diaphragm or condom alone are not considered adequate contraception)".*

## Risks and Discomforts

A comprehensible description of reasonable foreseeable harms/risks or inconveniences to the participant that may arise from research participation, as well as the likely consequences of non-action, particularly in research related to treatment, or where invasive methodologies are involved, or where there is a potential for physical or psychological harm.

Describe the risks, discomforts, inconveniences (physical, emotional, financial and social) to the participant as follows with the following headings, and bullets. List the most severe risks first in each section:
Common: (% incidence)
Less Common: (% incidence)
Rare: (% incidence)
Very Rare: (% incidence)
List all side-effects and explain the ramification of the risks.
List all side effects the participant needs to be aware of and what action to take
Who to contact in the event of a research-related injury

What are the possible benefits for taking part in the study

A comprehensible description of reasonably foreseeable benefits that may arise from research participation. When there is no intended clinical benefit to the participant, the participant should be made aware of this.

If the research participants themselves, other Participants with a similar condition or society may benefit from the participant's involvement I this study, this should be stated and the potential benefits described.
Potential benefits to the participant should not be overstates; it may create an inducement to the participation. Participants may already be predisposed to expect a benefit, and need to understand that benefits cannot be guaranteed.

"you may or may not receive direct benefit from this research study, however results from this study may further medical or scientific knowledge."

## Alternative Treatments

The alternative procedures(s) or course(s) of treatment that may be available to the participant, and their important potential benefits and risks.

Disclose any standard treatment that would be withheld if the person consents to participate.

A general statement of prognosis using conventional therapy should be included in cases where the prognosis is poor.

**Withdrawal from study**

The investigator or sponsor may withdraw you from this study at any time should it be in your best interest. Outlines reasons for withdrawal and withdrawal procedures

Outline that information already gathered will be kept and if tissue or biomarkers, what happens to the samples

If there are parts of the study in which the participant could choose not to participate, this should be clearly explained (for example, if there is a genetic sub study).

The right of the participant to withdraw at any time.

**New Findings**

The investigator will inform you of any significant new findings about the drugs being used in this study. Your willingness to continue participation in this study could be affected by this new information.

If there are new findings or changes you will be asked to sign an addendum to the information and consent form, or a revised consent. (Revise to suit study)

Indicate how the participant will be notified of the study results.

**Potential Costs/Reimbursements**

If there is compensation for participation (describe). Information on any reimbursements for expenses. (note that HUMBER RIVER HOSPITAL permits that study participants receive reimbursement for parking and meals for visits that are above standard of care, however do not approve of inducements

Costs to the participant

Does the investigator have any conflicts of interest?

**Compensation for study related injury**

Will medical treatment be available in the event of research related injury

"if you suffer research related side effects from (the medical device or procedure or taking the study medication or participation) in this study, medical care will be provided to you in the same manner as you would ordinarily obtain any other medical treatment. In no way does signing this form waive your legal rights or release the study doctor(s), sponsors or involved institutions from their legal and professional responsibilities."

"In no way does signing this form waive your legal rights nor release the study doctor, [company X], the study sponsor or Humber River Hospital from their legal and professional responsibilities.

**Confidentiality and Data Protection**

****Reminder to add clinical trials.gov info in the consents**

****Reminder to add PIPEDA info**

**In Canada, your privacy rights are regulated under the**

**Note: Clauses A. to K are needed in most Consents. The HRH-REB has a member exclusively responsible for confidentiality. Some alternatives are set out as not all paragraphs will be needed.**

A. All information obtained during the study will be held in strict confidence. You will be identified with a study number only. No names or identifying information will be used in any publication or presentations. No information identifying you will be transferred outside the investigators in this study. During the regular monitoring of your study or in the event of an audit, your medical record may be reviewed by **Note:** (Insert who may review).

**Note:** Set out who may have the review capability. Many USA forms do not contain the Canadian laws that Humber River Hospital REB require.

B. Your privacy rights are regulated under the Ontario Personal Health Information Protection Act, 2004 (PHIPA), as well as under certain provincial privacy and/or health information regulation. Among other things, such legislation is intended to protect your health information. This section explains how your health information will be collected, used, disclosed and describes your right to have access and review your personal health information under Canadian and Ontario laws of privacy.

**Note:** This clause lets the sponsor have the Participant's privacy information.

C. In working with the sponsor, **Note: (**Insert Sponsor's Name) your treating doctors and others assisting him/her with this program will need to use your personal health information and for the purpose of the study and the safety and effectiveness of: **Note:** (Insert study drug etc.) Your "personal health information" is health information about you that could be used to identify you because it includes information such as your name, address, telephone number, date of birth, health insurance number, new and existing medical records, or the types, dates, and results of various tests and procedures. This may include information in your medical record and information created or collected during the study. By signing this informed consent form, you allow your study doctor or staff to collect and use your personal information to carry out this study.

**Note:** The following clause does not provide the Sponsor with the Participant's identifying personal health information.

D. By signing this informed consent form, the data that the sponsor receives about you does not include your name, address, or health insurance number. Instead the study doctor uses your initials and assigns a code number to your records that are sent to the sponsor. However, your medical records may be reviewed or copied at the study site by the sponsor and/or its representatives, and may be reviewed or copied by regulatory authorities or other overseeing bodies, including the Research Ethics Board (REB) of Humber River Hospital. The purpose of these reviews is to make sure the program is being conducted properly and that the data is being collected correctly, or for other purposes that are allowed by law.

E. Your medical records may be reviewed and copies made by members of the (REB) research ethics board of the Humber River Hospital, regulatory agencies including Health Canada, the FDA in the USA or an authorized sponsor representative for the purposes of this study.

F. Personal health information (including information contained in your medical records) may, if necessary for any of the purposes as required by law, be disclosed to regulatory authorities and the research ethics board (REB) of Humber River Hospital, including Health Canada and the FDA in the USA or as required by law.

G. You will have a right to access your personal health information as well as the right to correct any inaccuracies in records containing such information. However, the scientific validity of the study depends on maintaining controls under which study participants cannot obtain certain information relating to which study medication they are receiving and/ or results from study procedures. Accordingly while you will generally be able to access your personal health information, there is limited study data that will not be accessible until after the completion of the study.

H. You have the right to withdraw consent to the processing of your personal health information as described above at anytime upon notice to the study doctor, however, you will thereafter no longer be able to participate in the study. Any withdrawal of consent will not affect uses or disclosures of personal health information before the date of withdrawal, users or disclosures needed to ensure scientific integrity of the study, or the continued use or disclosure of your personal health information and not identifiable format for the above purposes.

I. Unless withdrawn, this consent will remain in effect for up to, **Note: (**Set out time period) by the researchers and sponsor for the purposes of the study.

J. If you have any questions about privacy or the use of your personal health information you may call the Privacy Office of the Humber River Hospital. **Note:** Set out contact details.

K. According to Canadian laws only persons who had expressly consented to their personal data being recorded and reviewed can participate in a clinical study. The results of the clinical study will be forwarded in an anonymous form (i.e. without Participant names) to the sponsor of the clinical study. It is particularly important for research purposes and also for the safety of future Participants that the data is recorded correctly. In order to review the data, authorized representatives of the sponsor of the clinical study and the national and international health authorities such as Health Canada, the US Food and Drug Administration (FDA) and any

similar foreign government agencies and the (REB) research ethics board (an independent ethics committee that reviewed the ethical aspects of the study to help protect the rights and welfare of study participants) are permitted to examine the original findings and records of the clinical data at the study site. The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed. Your explicit consent is required for this. The persons appointed to review the data are bound to strict confidentiality and to observance of data protection. The Participant data will not be further communicated or conveyed. While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy

**Note:** The Humber River Hospital REB will review the confidentiality and privacy features to be certain the activities of the study to preserve the utmost of these privacy features for the Participant, therefore insert all the details as to how they will be achieved.

REB, regulatory authorities and relevant companies, etc, will have direct access (inspect and receive) to the participant's original medical records for verification of clinical trial procedures and/or data without breaching confidentiality.

To the extent permissible by the relevant laws, records identifying the participant will be kept confidential and not be made public. However, while every effort will be made to protect the privacy and confidentiality of your personal information, you should be aware that US legislation, namely the USA PATRIOT (Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism) Act of 2001, states that certain USA government bodies are allowed to access information held in the USA, on a need to know basis for government security purposes. Since this study will require sending study data to **(insert sponsor name)**, which has locations in the USA, it is important to know that this information may be accessed by the US governmental bodies without your knowledge.

Anticipated uses of data

The way(s) which the research will be published

How the participant will be informed of the results of the study.

## Data Protection

**Note:** In the below alternatives some are preferable to others depending on the study. Confidentiality and its procedure will be looked at in particularity.

**Note:** This alternative allows for disclosure of personal health information to the Sponsor.

1. In signing this informed consent form, you also allow the treating physician or study doctor to disclose your personal health information to the sponsor including representatives of the sponsor, who will use this information to evaluate the study drug **Note:** (Insert study Drug). Your information also may be shared with the research ethics board of this study and other health authorities in this country and other countries. The purpose of this disclosure to regulatory authorities and oversight bodies is to insure the study is being

conducted properly, to help and ensure that your rights and welfare as a participant are protected and that the study is carried out in an ethical manner or for other purposes that are allowed by law.

2. Neither the results from any samples taken will be identified by name. A code will be used in all documentation related to the study.

3. All exploratory samples will be coded using labels with a unique code number and all analysis results will be further coded by using a different unique bar-code for the samples.

4. Some of the procedures may contain confidential information and these may be sent to a central review facility for interpretation and reporting the results sent back to the sponsor. The confidentiality of the procedures will be maintained by staff members under contract with the sponsor.

5. Personal information, including medical and health data will be collected and used and managed by the principal investigator (the researchers), as well as the sponsor and their respective global subsidy to areas, affiliates and authorized agents for the purposes of conducting the study, obtaining future regulatory (marketing) approvals up for the study drug, and as needed.

6. It is a requirement that your involvement in this study is noted in your medical records. An authorized representative of the sponsor will have direct access to your medical records for the purposes of checking the information collected for the study.

7. Personal health information will be used and maintained in an identifiable form by the researchers. The sponsor will use and maintain your personal health information in a non- identifiable form. However, the sponsor, during the course of a regular monitoring visit, may review your medical record for comparing that the de-identified information is the same as the information contained in your medical record. Additionally, your name and personal information will be visible on your radiology images. The sponsor and any agents assisting the sponsor will uphold confidentiality of your information as best they can but still be required to perform the procedures and ethical duties.

What participant identifiers will be used on data collection forms (e.g., names, initials, DOB)?

How will data be stored? (Computerized files, Audio recordings, Hard copy, Video tape, Other (Please specify

## PARTICIPANT STATEMENT AND SIGNATURE

### Consent to Study

I confirm that I have read the statements in the informed consent form for this study. I confirm that the study information and procedures have been explained to me during the consent process for this study.

I confirm that I have had the opportunity to ask questions about this study and I am satisfied with the answers and explanations that have been provided.

I have been given time and opportunity to read the information carefully, to discuss it with others if I wished to and to decide whether or not to take part in this study.

I have had all alternative treatments discussed with me.

I agree that (COMPANY) research using my medical data may lead to the development of commercial pharmaceutical products. (COMPANY) and other researchers may use these data and may patent or commercialize discoveries or inventions that result from this research. Neither (COMPANY) nor other participants in this research will compensate me if this happens.

I authorize the release of my medical records as outlined in this consent form.

I grant permission to inform my family doctor about my participation in this study. □ Yes □ No □ N/A

If I have questions, I can meet with my doctor, or the doctor who is in charge of the study at this institution. That person is **Dr. @**

Or, I can talk to someone who is not involved with the study at all, but who can advise me on my rights as a Participant. That person is **Dr. Lisa Chiang (Research Ethics Board Chairperson) @ 416-243-4562**.

I agree to take part in this study. I will be given a copy of this signed and dated consent form.

**I FREELY ACCEPT TO PARTICIPATE IN THIS STUDY**
*(The consent form is to be signed by all parties on the same day (simultaneously)*

| _____ | _____ | _____ |
|---|---|---|
| **Printed Name of Participant** | **Signature of Participant** | **Date** |

**Person Conducting the Informed Consent Process**

| _____ | _____ | _____ |
|---|---|---|
| Print Name of Person Obtaining Consent | Signature | Date |

**Written Consent by Legally Authorized Representative *(if participant is unable to sign*)**

| | |
|---|---|
| Printed Name of Legally Authorized Representative | Relationship |
| Signature of Participant's Legally Authorized Representative | Date |

**Investigator Statement**
I have discussed this project with the participant and/or his/her legally authorized representative using a language which is understandable and appropriate. I believe that I have fully informed the participant and/or legally authorized representative of the nature of this study and its possible benefits and risks, and I believe that the participant and/or legally authorized representative understood this explanation.

| | | |
|---|---|---|
| Printed Name of Investigator | Signature of Investigator | Date |

**If Applicable:**

**Impartial Witness:** applicable if the participant, or legally authorized representative, is unable to read.

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

**Translator:** applicable if consent process done in language other than English.

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

Language of Translation

cc: Health Record