GENERAL INFORMATION YOU NEED TO KNOW WHEN PARTICIPATING IN A RESEARCH STUDY

INTRODUCTION:

You are receiving this document because you have been asked to participate in some type of research activity within Horizon Health Network. This document contains general information that all research participants should know. The person in charge of your particular study (referred to as the Principal Investigator or Study Doctor), or delegate will go through an informed consent process with you and provide detailed information that is specific to your study. This process will include the signing of a study specific informed consent document. You should take all the time you need and ask any questions you have before signing that document.

The purpose of the present document is to provide you with standard information that applies to all research studies. In particular it will:

1) explain that your participation is voluntary,

2) provide information about possible risks that you might be exposed to,

3) provide information about your privacy and confidentiality rights,

4) provide information about what to do if you are injured,

5) provide the contact information to resolve any questions you may have about your rights as a research participant or privacy/confidentiality concerns, and

6) explain the responsibilities of research participants,

7) provide a brief description of what you can expect from the study specific informed consent process with your study doctor.

SECTION 1: VOLUNTARY PARTICIPATION

Medical Treatment vs Medical Research: A research study is different than regular medical treatment. Research is intended to further the goals of science; whereas, regular medical treatment is intended to address your specific health care needs. It is important that you understand that there is no guarantee that your specific health care needs will be addressed if you choose to participate in a research project.

Doctors who do research as well as treat patients: Frequently, the "study doctor" will be your treating physician. In this circumstance you must realize that your treating physician is in a "dual role," in other words, he/she is a scientist (for research purposes) and a physician (for treatment purposes). A misconception can occur when a patient thinks that, since his or her physician proposed a research study, participation is in their best interest, when in fact, it might not be. Your treating physician/study doctor will make special efforts to explain this dual role to you and to make sure you appreciate that you are participating in a research project, which is totally different than receiving medical care.

Your Medical Care: The decision not to participate in a research project will not negatively impact your regular medical care – this is what voluntary participation means. There are absolutely no negative consequences associated with a decision not to participate in a research project.

Withdrawal of Consent: If you decide to participate in a research study, you can withdraw your consent to participate at any time, for any reason. If you withdraw your consent, the study doctor is required to ask why you have made the decision; but it is up to you whether or not you provide your reason(s). You may also instruct the study doctor to withdraw any information about your study participation; if this is not possible the study doctor must explain why this cannot be done during the study specific informed consent process.

Your Primary Care Provider: If you choose to participate in a research study, Horizon Health Network policy requires that the study doctor notify your primary care provider of your study participation. This is so that everyone in the circle of care is aware if there is an emergency.

SECTION 2: RISK DISCLOSURE

Phase of Research: Research participants may be exposed to risks by participating in a research project. It is important that you understand all of the risks associated with your research participation. The specific risks you might be exposed to will depend on the particular study that

you are participating in. However, in general, the risks of research and the goals of research are connected with the "phase" of the research project. As a potential research participant this is important information for you to know. Phase III research is typically focussed on finding a treatment or cure; whereas, Phase I and II research typically focusses on testing how much of a drug can be safely given to a person. Here are descriptions of each phase, please ask your study doctor which one applies to your specific research project:

- **Phase I clinical trial:** Clinical trials designed mainly to determine the way a drug works and the safety (side effects) associated with increasing doses. Phase I trials are generally conducted in healthy volunteers, but may be conducted in patients when administration of the drug to healthy volunteers is not ethical.

- **Phase II clinical trial:** Clinical trials to evaluate the effectiveness of the drug in patients with medical conditions to be treated, diagnosed or prevented and to determine the side effects and risks associated with the drug. These trials provide preliminary information on the safety and effectiveness of the drug in patients.

- **Phase III clinical trial:** Controlled or uncontrolled trials conducted after preliminary evidence suggesting effectiveness of the drug has been demonstrated. These are intended to gather the additional and confirmatory information about the clinical effectiveness and safety under the proposed conditions of use for the drug.

- **Phase IV clinical trial:** All studies performed within the approved indication after the drug has been approved by the regulator for the market (e.g., Health Canada, the US Federal Drug Administration). These trials do not usually require regulatory approval by Health Canada.

Risk Disclosure: Your study doctor will disclose everything he or she knows about the risks associated with your particular study. The study doctor will identify and describe all foreseeable harms, including physical, emotional, psychological, social, legal, and any financial harms or inconveniences. The study doctor will describe how much experience there is to date with the new drug/device or procedure and explain any possible interactions with the study drug and other medications. Most importantly, you should be aware that there is always the possibility that very uncommon or previously unknown side effects or risks may occur. If questionnaires or surveys are used the study doctor will explain that some of these questions may be distressing as well.

Risk Frequency: In addition to disclosing all of the risks, the study doctor will gauge the risks as well. First, he/she will list the risks by severity, for example, life threatening, severe, moderate, or mild; then he/she will provide an estimate of the likelihood of the risk materializing, for example "greater than 10%," between 1%-10%, and "less than 1%." This

information will be provided in point form and he/she will explain if the potential harms are reversible.

Reproductive Risks: The study doctor will explain if there is evidence available showing potential harm to the male sperm and/or the fetus/embryo from the investigational product. Typically to participate in a research study some form of contraception, by both male and female participants, is required. This is because the effects of the research drug on the fetus/embryo might not be known. The study doctor will tell you if any forms of contraception are not permitted and also what will happen if you do become pregnant (or get someone pregnant).

Potential Benefits: The study doctor will also explain any reasonably expected benefits of research participation. If there is no intended clinical benefit for you this will be emphasized. One of the most important benefits of research is the potential for helping future patients who will need access to better drugs, treatments, etc.

Alternatives to Participation: The study doctor will discuss the treatment options available if you decide not to participate in the study; this will include a discussion of what the current standard of care is at this institution. If the study drug/intervention is available outside of the trial, he/she will explain this as well.

New Developments: If this study is changed in any way which could affect your willingness to continue your participation, you will be told about the changes and may be asked to sign a new informed consent form. Also, it is important to realize that your participation may be stopped if the study doctor decides that it is in your best interest or at the discretion of the sponsor.

General Understanding: After you go through the informed consent process with the study doctor you should understand the purpose of the research, the risks, any potential benefits and what is expected of you as a research participant.

SECTION 3: PRIVACY AND CONFIDENTIALITY

Privacy: It is important for you to understand how participating in this research study will impact your privacy and confidentiality. The research team will comply with all privacy and confidentiality laws and/or policies. However, you should be aware that the study doctor will be collecting the following information from different sources:

- information from you,
- information from your health record,

- this information will be shared with the people conducting the study,
- this information may be shared with the people responsible for protecting your safety as a research participant.

Access to Records: The study doctor and members of the research team will see health and study records that identify you by name. Other people may need to look at the health and study records that identify you by name as well. These might include:

- the study sponsor and people working for the sponsor,
- representatives from Health Canada,
- other regulatory agencies such as the United States Food and Drug Administration, and/or,
- the Horizon Health Network Research Ethics Board.

Unless the Principle Investigator provides reasons to the contrary, you are permitted access to the information that has been collected about you.

Coded Information: The study doctor will code your information before sharing it with anyone. This means that the information is protected by the use of a code which is an assigned number specific to your study file only. The study doctor is in control of the key which is needed to decipher the code.

Use of Records: The research team will collect and use only the information they need to conduct the study and judge the safety and usefulness of the study drug. This information will include:

- Date of birth
- Gender (male/female)
- Medical Conditions
- Medications
- Results from tests and procedures you had before, during and after the study
- Information from study interviews and questionnaires.

The trial sponsor may use your information to conduct the study, to support applications for approval of the study medication and for research related to the development of pharmaceutical products, diagnostics or medical aids.

The trial sponsor may share your coded information with other companies within its group, with its service providers, its contractors and with other research institutions.

Other Countries: The trial sponsor may transfer your coded information to countries outside of Canada for purposes the study doctor will explain. All information that is transferred by the trial sponsor outside of Canada will be coded and will be transferred in compliance with the trial sponsor's internal privacy policies, subject to the local laws and regulations that may be applicable in the country where data is transferred.

Publication: The results of the study may be published but you will not be identified and your information will not be shared with others without your permission. Your name will not appear in any report or article published as a result of this study.

Information Retention: Information collected for a research study will be kept as long as legally required, which could be up to 25-years or possibly more. Your information will be kept secure by the research team at the site where the study is being conducted. The study doctor will explain the specific requirements for your study.

SECTION 4: RESEARCH RELATED INJURY

Injury: If you become ill or injured as a result of participating in this study, the Principal Investigator will ensure that you receive medical care at no cost to you. By signing this form you are in no way waiving your legal rights or releasing the Principal Investigator and Sponsor from their legal responsibilities.

SECTION 5: CONTACT INFORMATION

Phone Numbers and E-Mail: In the event that injury, illness or disability results and you believe that it is related to your participation in this study, or if you have any questions about your rights as a research participant, you may contact the Regional Director of Ethics Services at (506) 648-6094 or by e-mail at REBOffice@HorizonNB.ca. If you have any questions or concerns about your privacy rights you may contact the Privacy Officer for Horizon Health Network at the toll free number 1-877-422-8717.

Compensation: The study drug/device will be free of charge and there will be no charge to you for clinical examinations, laboratory tests, or any other medical treatment which you may require as a result of your participation in a study. Reasonable out of pocket expenses, if any, associated with your participation may be reimbursed. The study doctor will explain the details for your

particular study. Sometimes research findings lead to the development of commercial products. As a research participant you should not expect to profit from any such development.

SECTION 6: PARTICIPANT'S RESPONSIBILITIES

Your Responsibilities: As a participant in a research study it is in your best interest to be entirely truthful about your medical history and lifestyle choices (e.g., recreational drug use). If you are not completely truthful with the study doctor you may be harmed by participating in a research study. In order for these projects to be valid and complete, it is important that you comply with the requirements of the study (e.g., visit schedule, questionnaires, medications, etc.). These commitments should be carefully considered before agreeing to participate in a research study.

Additional Information: The Principle Investigator will provide you information for reporting problems or for asking study related questions. In a separate form, he or she will provide you with a contact person who is knowledgeable about the study to which you are being recruited. You will also be provided with contact information and procedures in the event of an emergency.

SECTION 7: STUDY SPECIFIC INFORMED CONSENT FORM

The Research Ethics Board has prescribed information that study doctors must include in the study specific informed consent forms. Here are the instructions given to them:

1. Please describe the objectives, purpose, and duration of the research study.
2. Please describe the population of people to be included and why this participant qualifies to be included in the study.
3. Please describe the experimental intervention to be tested, e.g., study drug, device, new technique, etc.
4. Since research projects frequently compare different groups, please describe the groups that will be compared.
5. Please explain how participants will be assigned to the different comparison groups. (Frequently randomization is used to assign participants to groups, which is like flipping a coin; other studies might involve assigning participants to receive a placebo, which is an inactive substance like a sugar pill.)
6. Describe the primary outcome(s) to be studied.
7. State the expected number of participants, the scope of the study (e.g., national or international), and how many participants locally and overall (e.g., Fredericton = 10 and North America 100 at 10 sites).

8. Briefly explain the study design and methods of treatment the participants will undergo if they agree to participate. Clarify what procedures the participants will undergo solely for research purposes (e.g., the number of blood draws). Specify the number of required hospital visits/clinic visits, whether inpatient or outpatient, and the actual time commitment involved in participating. Outline the procedures for each visit in point form and provide the time interval between each visit, for example,
    - Screening visit (obtain informed consent)
    - Visit 1 (2 weeks after screening)
9. Describe the alternative procedure(s) or courses(s) of treatment that may be available to the subject, and their potential benefits and risks.
10. Provide a contact name and number of someone knowledgeable about the study and what to do in the case of an emergency.
11. Provide a copy of the signed informed consent form to the participant.

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

PARTICIPANT'S QUESTIONS:

Have you had an opportunity to ask questions and discuss this study?	☐ Yes	☐ No
Are you comfortable with the information that has been provided?	☐ Yes	☐ No
Do you understand that you are free to withdraw from this study?	☐ Yes	☐ No
Do you understand that you will receive a signed copy of this consent?	☐ Yes	☐ No

Printed Name of Participant/ Substitute Decision Maker	Signature of Participant/ Substitute Decision Maker	Date
Printed Name of Person Conducting Informed Consent Discussion	Signature of Person Conducting Informed Consent Discussion	Date

PI:
RS#:
Protocol:
Date:

Printed Name of Witness (Optional)	Signature of Witness (Optional)	Date

INVESTIGATOR'S/DELEGATE'S STATEMENT

I, or delegate, have explained to the above participant the general information that any participant is required to know prior to participating in a research study. I have answered any questions that have been raised. I believe that the participant understands the implications and the voluntary nature of the study.

Investigator/Delegate (Print)	Signature	Date

PI:
RS#:
Protocol:
Date: