INSTRUCTIONS FOR CREATING YOUR STUDY SPECIFIC INFORMED CONSENT FORM

There are two types of Informed Consent Forms (ICF), the generic ICF and the study specific ICF. The generic ICF has been prepared for you and cannot be altered. It provides general information that anyone participating in a study needs to know and has seven sections: Voluntary Participation, Risk Disclosure, Privacy and Confidentiality, Research Related Injury, Contact Information, and Participant's Responsibilities. The informed consent process should include a careful review of this document. However, it is appropriate to highlight certain sections as being more pertinent to the specific study than other sections.

The study specific ICF should be concise and really inform the participant about the details of the particular study he or she is considering. Throughout the generic ICF, Principal Investigators are directed to disclose study specific information to research participants; there are 12 of these statements and at the end of the generic ICF more instructions are provided.

For your convenience the 12 statements and instructions are reproduced in this document. The following are quotations taken from the generic ICF.

> **Doctors who do research as well as treat patients:** 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. (p.2)
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> **Withdrawal of Consent:** 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. (p.2)
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> **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. If questionnaires or surveys are

used the study doctor will explain that some of these questions may be distressing as well. (p.3)

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. (p.3)

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. 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). (p.3-4)

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. (p.4)

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. (p.4)

Access to Records: Unless the Principle Investigator provides reasons to the contrary, you are permitted access to the information that has been collected about you. (p.4)

Other Countries: The trial sponsor may transfer your coded information to countries outside of Canada for purposes the study doctor will explain. (p.5)

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. (p.6)

Compensation: Reasonable out of pocket expenses, if any, associated with your participation will be reimbursed. The study doctor will explain the details for your particular study. (p.6)

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. (p.7)

In addition to the information outlined above please include the information below in the appropriate section(s) of the study specific informed consent form (the suggested section is listed in italics):

1. Please describe the objectives, purpose, and duration of the research study. *(Purpose Section)*
2. Please describe the population of people to be included and why this participant qualifies to be included in the study. *(Purpose Section)*
3. Please describe the experimental intervention to be tested, e.g., study drug, device, new technique, etc. *(Study Outline and Procedures Section)*
4. Since research projects frequently compare different groups, please describe the groups that will be compared. *(Study Outline and Procedures Section)*
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.) *(Study Outline and Procedures Section)*
6. Describe the primary outcome(s) to be studied. *(Study Outline and Procedures Section)*
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). *(Study Outline and Procedures Section)*
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) *(Study Outline and Procedures Section)*
9. Describe the alternative procedure(s) or courses(s) of treatment that may be available to the subject, and their potential benefits and risks. *(Potential Risks/Discomforts Section)*
10. Provide a contact name and number of someone knowledgeable about the study and what to do in the case of an emergency. *(Questions Section)*
11. Provide a copy of the signed informed consent form to the participant.