PARTICIPANT INFORMATION AND CONSENT FORM

PART I: REQUIRED ELEMENTS OF INFORMED CONSENT

When developing your participant information and consent form for The University of Manitoba Bannatyne Campus Research Ethics Board, please ensure that you address all of the following requirements:

INFORMATION FOR PARTICIPANTS

1. Clearly explain the purpose of the research and include a statement that the individual is being asked to participate in a research study.
2. State the expected duration of the participant's participation. Provide an estimate of the amount of time required for each visit, the overall number of visits, and the length of time that the participant will be required to participate to complete the research study.
3. Describe all of the procedures, tests, drugs, questionnaires, etc. that will be used, identifying any that are experimental, placebo, and/or beyond standard procedure. Identify which is routine care and which is added for research purposes. Be clear about what interventions are above and beyond the usual care that participants would receive i.e. CT scans, etc. The University of Manitoba Bannatyne Campus Research Ethics Board, requires full disclosure regarding which procedures related to research are paid for by the Sponsor. Any risks to participants should be clearly stated.
4. Describe any previous experience with humans; include the numbers of participants involved where available.
5. Describe any appropriate alternative procedures or courses of treatment to what is being done as part of the research. Include a statement that the participant may elect to receive standard treatment instead of participating in research.
6. Provide a statement that the particular treatment may involve risks to the participant which are currently unforeseeable; (or to the embryo or fetus if the participant is or becomes pregnant).
7. Describe any known and reasonably foreseeable risks and discomforts that the participant may experience. Quantify risks wherever possible (e.g. "less than 2%" rather than "rare").
8. Clearly describe any benefits, or lack of benefits, that the participant or others may experience.
9. Include a statement that any significant new information, which becomes available during the research, which may relate to the participant's willingness to continue participation, will be provided to the participant.
10. Provide the approximate number of participants overall who will be involved in the research in total across all centres if this is a multi-centre trial.
11. Provide a statement that participation is voluntary, that the participant may refuse to participate, and that participation can be terminated by the participant at any time without prejudice. Provide instructions on how to exercise this right(note: written notification is not required).

12. Provide a statement that the participant's participation may be terminated by the Investigator or Sponsor without the participant's consent. Examples might include: the participant's medical best interest, funding is stopped, drug supply is insufficient, participant 's condition worsens, new information becomes available, failure to take the medications as described, etc.

13. List any requirements to disclose medications, alcohol or drugs currently being taken and any restrictions that are required to remain in the clinical trial.

14. Provide a statement indicating the potential financial conflicts of interests of the investigator and institution. Sample text has been provided in the consent form templates.

OPEN LABEL EXTENSION PHASES

15. Note that the University of Manitoba Bannatyne Campus Research Ethics Board will request a separate Informed Consent Form be signed for the open label extension phase of the trial.

REGARDING WOMEN AND CHILDREN

16. Provide a statement that medication should be kept out of the reach of children and others for whom it is not intended.

17. Provide a statement with regard to any specific individuals who should not participate in the study such as pregnant or breast-feeding women.

18. Provide information about acceptable methods of birth control for women of childbearing potential or for men who are sexually active. The exact methods of birth control required will be stated in the protocol and will be dependant on the known toxicities of the drug/drugs or devices under study.

STORAGE OF BLOOD AND TISSUE SAMPLES

19. Note that The University of Manitoba Bannatyne Campus Research Ethics Board will not provide approval for consent of the use of information, blood, or tissue samples beyond those directly related to the research described in the protocol and consent form under review. Long term storage of any blood or tissue samples for use other than that described in the protocol and the approved consent may be acceptable to The University of Manitoba Bannatyne Campus Research Ethics Board only through clear information and consent.

20. A separate informed consent is required for storage of blood and tissue samples that are stored beyond the length of the study.

COMPENSATION

21. Describe any methods and amounts of payment or reimbursement for expenses that would result from participant participation. Ensure that such payments are not undue incentives or excessive to the point of being considered coercive. Financial compensation is expected to reimburse the participant for time and out of pocket expenses that result from participation in the study. Financial compensation that could influence the participant's judgement is not acceptable.

22. Provide a statement as to whether compensation and/or medical treatment are available if a research related injury occurs and where further information may be obtained. A sample compensation for injury statement has been developed by the University of Manitoba Bannatyne Campus Research Ethics Board for the Participant Information and Consent Form.

23. Include a description of any additional costs to the participant as a result of participation in this research.

CONTACTS FOR PARTICIPANTS

24. Provide the name(s) and phone number(s) of the research doctor and/or research staff who may be contacted for information on research-related questions and research related injury.

25. Provide the phone number of the University of Manitoba Bannatyne Campus Research Ethics Board (204 789-3389) to ensure objective input to questions that the participants may have about their rights when participating in research.

CONFIDENTIALITY FOR PARTICIPANTS

26. Include a statement of confidentiality that describes how the information from the research and the participant's identification will be distributed or protected**.** Indicate how information will be de-identified before it is distributed outside the study centre. Include a statement that The University of Manitoba Health/Biomedical Research Ethics Board, the Sponsor/Drug Company and their representatives, the Food and Drug Administration, and the Health Protection Branch will have access to the participant's confidential records but that all are committed to confidentiality as well. A statement that the identity of the participant will be protected, but due to access from all of these groups, it cannot be guaranteed. Include a statement that the participant will not be identified in any published data, that their identity will be treated as confidential in accordance with the Personal Health Information Act of Manitoba and that information will only be used for research purposes.

FORMAT

27. Write the consent form in simple language that is understandable to the general public. Do not use technical or medical language. Write to a grade 6-7 level of understanding.

28. It is preferable to use the word "participant" to refer to the individual who is consenting to participate in the research study.

29. Avoid language that implies judgment, bias, or guilt.

30. Be consistent with the use of pronouns so that there is no confusion regarding who is the participant and who is the investigator. Be consistent and clear when using first vs second person.

31. Each page of the consent form, paraphrase, or information sheet needs to state the exact title of the approved protocol as a header or footer. State the page number as well as the total number of pages (e.g. 1 of 5 pages). The bottom of each page will need to have a designated place for the participant to initial to show that they have reviewed each page.

32. The final section of the consent must be written in the first person (as "I" statements) and include a statement that the participant has been informed of the titled study and that they have had all of their questions answered. A statement that the participant agrees to participate in the research is also required. Restate the right to confidentiality and the right to decline participation or to withdraw. Include a sentence indicating that the signing of the document does not waive any of the legal rights of the participant. Include a statement that the participant will be given a copy of the consent for their records. (The copy provided to the participant does not have to be a signed photocopy of the original as long it is the exact same consent form that was signed).

33. The consent must have a place for the participant to sign their name, print their name, and date the signature. *For third party signatures, the consent will also have a place for a witness to sign their name, print their name and date their signature. By signing the consent form, the witness attests that the information in the Participant Information and Consent Form was accurately explained to and apparently understood by, the participant or the participant's legally acceptable representative and that informed consent was freely given by the participant or the participant's legally acceptable representative. If the participants are children, include a place for the child to sign their assent along with the name and signature of the parent or legal guardian. A separate simplified assent form should be developed for children.

34. A last section of the consent, after the participant signs, will be a statement that the protocol has been explained to the participant and that the participant appears to have understood the research study. This section will be signed by the research study staff individual who has explained the study and obtained the consent. This signature can be the same as that of the person witnessing the consent. This is a measure to ensure accountability that the participant has been provided with sufficient information to give informed consent.

35. If verbal translation is required, this should be indicated on the Participant Information and consent form. The printed name, signature and date of signature of the translator should be added.

36. For consent forms that are in a language other than English or French, please provide written documentation stating that they have been translated and back translated to assure consistency with the approved English version.

37. The participant information and consent form should be revised whenever important new information becomes available that may be relevant to the participant's consent. Any revised participant information and consent forms should be reviewed and approved by The University of Manitoba Bannatyne Campus Research Ethics Board prior to use.