OPTIMUM CLINICAL RESEARCH INC. ETHICS REVIEW BOARD
604 TAUNTON ROAD WEST, OSHAWA, ONTARIO L1L 0N9

PLEASE COMPLETE THIS FORM, AND Email to: info@optimumerb.ca

*** *2023* SITE QUESTIONNAIRE***

Please complete this questionnaire ***in its entirety*** and return to Optimum. A completed questionnaire will be kept on file for each site, for each protocol. ***Unless otherwise indicated, the information that you fill in below will appear on the front of your final stamped consent form that you will receive from Optimum.***

PLEASE PRINT CLEARLY – DO NOT LEAVE BLANKS
If print is not clear, this may result in a delay.

Name of Clinic/Site Name:_____

Address:_____

City:_____ Province_____ Postal Code_____

Main Tel #_____ Fax #_____

Name of Principal Investigator(s) _____

Name of Co-Investigator(s)_____

Co-Investigator(s) Address(es) (if different from PI Address)_____

_____

Study Coordinator(s)_____

EMAIL address for communication from Optimum (will not be included on ICF):

_____

PROTOCOL INFORMATION:

SPONSOR:_____

PROTOCOL NUMBER (or other identifying information) *please do not leave blank*:

_____

1) How long has your site been conducting clinical research?
□ 0-2 years □ 2-5 years □ 5-10 years □ more than 10 years

2) Approximately how many research studies has your site conducted in the last year?____

3) Has your site and/or the investigator been audited by a governmental regulatory authority?

□ Yes □ No If yes, when did this audit occur?_____

What was the outcome of this audit?_____

4) Describe your facility (attach a brochure, if available):
□ Hospital □ Public Health Clinic □ Private Clinic
□ Other: (please describe):_____

5) How close is your site to a hospital with emergency facilities?_____

6) Do you have emergency facilities available on-site in the case of an emergency?
(Ie. Crash cart, etc.) □ Yes □ No

7) Are there any community attitudes in terms of religious, ethical, ethnic, or economic attitudes which will affect the conduct of any research at your site? □ Yes □ No
If yes, please describe:_____
_____
_____

8) If you enroll non-English speaking subjects, do you use a translated consent form?
□ Yes □ No

If yes, into what other language(s) will you require the forms **for this study** to be translated?
_____

Do you have someone at your site who is capable of explaining the study and answering questions in the language of the non-English speaking subject? □ Yes □ No

9) Have you ever had a subject seek compensation for injury as a result of their participation in a clinical research study? □ Yes □ No

If yes, were there problems resolving it?_____
_____

10) Have you submitted this protocol to another ethics board prior to this submission? □ Yes □ No
If yes, please attach details of the other Board's findings and outcome of the submission.

11) Information to be inserted into your site-specific consent form (please note: if you require translated consent forms, you must also include the clearly printed or typed translation of any additional wording used):

a) Contact Information for Subjects for Study-related Questions

Name_____Tel:_____

b) Contact Information for Subjects in case of an emergency/adverse event *(if different from (a))*

Name_____Tel:_____

c) COMPENSATION FOR PARTICIPATION: This information will be inserted into your site-specific consent form: **(Please choose one of the 4 options)**

□ **I will compensate subjects for study-related expenses.**
(Addition to Consent Form will be: *"There will be no costs to you as a result of your participation in this study. You may be reimbursed for out-of-pocket study-related expenses, such as parking, taxi, etc.*"

□ **I will compensate subjects a specific amount for each study visit.**
(Addition to Consent Form will be: "*There will be no costs to you as a result of your participation in this study. You will be compensated in the amount of _____ for each study visit, to cover study-related expenses, such as parking, taxi, etc.*" (Please fill in the amount per visit, or indicate a maximum amount per visit)

□ **I will not compensate subjects.**
(Addition to Consent Form will be: "*There will be no costs to you as a result of your participation in this study.*"

□ **I will compensate subjects and would like to add the following as my statement:**
(Insert your preferred wording) Addition to Consent Form will be:

*****Please note: if you require translated consent forms, you must also include the clearly printed or typed translation of the proposed wording to be used:**

_____

_____

(Attach an additional sheet if necessary. This wording will be reviewed by the Board (or by the Chair) prior to insertion)

PLEASE ENSURE THAT ALL OF THE ABOVE QUESTIONS ARE ANSWERED FULLY AND ACCURATELY.

ACKNOWLEDGEMENT:
I agree to comply with any requirements set out by the Ethics Review Board and to promptly report to the Board all changes in research activities and any unanticipated problems involving risks to research subjects under my care, and the care of any Co-investigators for whom I am responsible. No changes will be made to the research or the consent form without prior approval by the Ethics Review Board. The information in this Site Questionnaire is true and accurate. Either the Investigator or someone under the Investigator's supervision will orally explain the informed consent to all prospective subjects before obtaining their signed informed consent. This protocol has not been refused approval by another Ethics Committee, under our submission.

_____ _____
Principal Investigator Signature (or designee) Date

_____
Printed Name of Principal Investigator (or designee)