SCARBOROUGH HEALTH NETWORK RESEARCH ETHICS BOARD
ANNUAL RE-APPROVAL FORM FOR RESEARCH STUDIES

Please note, as of January 1st 2019, all researchers are required to have TCPS2 Certification. If you have not already done so, please provide your certificate.

SHN PROTOCOL NUMBER	
PROJECT TITLE	
LOCAL PRINCIPAL INVESTIGATOR	
CONTACT INFORMATION FOR INVESTIGATOR (address, phone number, email address)	
Signature of Principal Investigator:	Date:

Please note: If there are sections that are blank, the entire form will be returned to be completed

Progress of study: (✓)

- ☐ Not Activated
- ☐ On Hold
- ☐ Interim Analysis
- ☐ Active Enrolment
- ☐ Closed to Enrolment
- ☐ Final Analysis in progress
- ☐ Abstract(s) attached
- ☐ Health Chart/Databases only

Number of subjects/charts enrolled to date at SHN: _____
****If this is none, please go to question A to complete****

Target number of subjects/charts at SHN: _____

Number of subjects/charts enrolled Study Wide: _____

Number of subjects/charts withdrawn: _____

FOR CLINICAL INTERVENTION TRIALS ONLY: For drug or device trials, indicate the **phase** of the trial (✓).

Phase I	☐ (initial use in humans; to determine the safest dose, route and schedule for a new drug; to identify toxic side effects)
Phase II	☐ (to provide preliminary information about how well the drug works; to generate more information about safety and benefit of the drug)
Phase III	☐ (to compare a new drug or combination of drugs or a procedure with the current standard therapy; to obtain additional safety and efficacy data)
Phase IV	☐ (following regulatory approval of the drug; study drug is used for the approved indication; to determine if efficacy can be improved)

Submit signed original: Research Office, Scarborough Health Network, 3050 Lawrence Avenue East, Room 1.245, 1st Floor, Scarborough, Ontario, M1P 2V5

Version: December 2018

A. If there are no subjects enrolled in this study, please explain rationale for renewal.

B. Please indicate if this study is complete and if the file can be archived.
☐ Yes ☐ No

If YES, please complete and attach a study completion form

C. Has your relationship with the study sponsor changed?
☐ Yes ☐ No ☐ N/A

If yes, please describe. Arising from the changes, are there any potential conflict of interest issues? Please declare here and initiate discussion with the Research Manager or Chair of the Research Ethics Board.

D. Is there anything new in the literature that may affect the study design or information provided in the consent forms? Please state source and comment.
☐ Yes ☐ No ☐ N/A

E. Please confirm that any study amendments proposed in the past year have been submitted for REB approval otherwise enclose here. (There is no need to list the already-submitted amendments here.)
☐ Yes ☐ No ☐ N/A

If Yes, date of last study amendment submission

F. Does this study have a Data Safety Monitoring Committee (DSMB)?
☐ Yes ☐ No ☐ N/A

If Yes, date of last submission: _____

If No, please explain rationale for no DSMB:

G. Please confirm that all Internal and External (Global) unexpected or serious adverse events (as per reporting requirements) have been submitted to the REB for follow up. Attach any outstanding reports here.
☐ Yes ☐ No ☐ N/A

Submit signed original: Research Office, Scarborough Health Network, 3050 Lawrence Avenue East, Room 1.245, 1st Floor, Scarborough, Ontario, M1P 2V5

Version: December 2018

H. Have you encountered any challenges/concerns in the course of the study over the past year including recruiting subjects, obtaining consent, subject compliance, interaction with sponsor, interaction with hospital)?
☐ Yes ☐ No ☐ N/A

If yes, please describe

I. If you are still recruiting subjects, what is the date of the consent form currently in use?

Version Date: _____

IF ENROLMENT IS STILL ACTIVE PLEASE READ THE FOLLOWING:

For all research requiring patient consent, please attach 1(one) copy of the current approved consent form.