SOUTHLAKE
REGIONAL HEALTH CENTRE

596 Davis Drive
Newmarket, Ontario
L3Y 2P9

Tel. (905) 895-4521, ext. 2763
Fax. (905) 952-3068
Website: www.southlakeregional.org
REBsubmissions@southlakeregional.org

Research Department

Research Ethics Board: Annual Renewal

Date of this submission: _____

A. Study Information

A.1. Study Title:

A.2 SRHC REB Number:

A.3 Name of local Qualified Investigator:

A.4 Name of Trial Coordinator: ❑ N/A

B. Approval History

B.1 Date of original SRHC REB Approval: _____

B.2 Type of Review: ❑ Full Board ❑ Delegated

B.3 Current expiry date: _____

C. Confirmation Information

C.1 What is the version #/date of the protocol/amendment currently in use: ❑ N/A

version #_____ _____

C.2 What is the version #/date of the consent form currently in use: ❑ N/A

version #_____ _____

D. Enrollment Status (check all that apply)

D.1 Chart review/specimen collection only, number of charts/records/specimens accessed to date:

Total accessed up to and including the following date: _____ ❑ N/A

Total charts/specimens accessed _____ ❑ N/A

For all other studies: (please check appropriate box)

D.2 ❑ No enrollment to date: *(please explain)* _____ ❑ N/A

D.3 ❑ Currently enrolling: ❑ N/A

D.4 ❑ Enrollment complete, participants in follow up ❑ N/A

D.5 ❑ Post treatment follow-up: *(data collection)* ❑ N/A

D.6 ❑ Enrollment complete, follow-up complete; data analysis etc. only continuing: ❑ N/A

SL0769_09 (10/12) "Research Department" Review (10/15)

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D.7 If Participants have been enrolled in study ❑ N/A

D.7.1 Number of Participants consented: _____.

D.7.2 Number of screen failures: _____.

D.7.3 Number of Participants withdrawn: _____.

D.7.4 Number of Participants lost to follow-up: _____.

D.7.5 Number of Participants deceased: _____.

D.7.6 Number of Participants on study follow-up: _____.

D.7.7 Number of Participants who completed study: _____.

(Note: Box D.7.1 should equal the total of boxes D.7.2 through D.7.7)

E. Study Concerns

E.1 Number of reportable deviations: *(as defined in SRHC policy)* _____.

E.2 Have all reportable deviations at the SRHC site been reported to the SRHC REB: *(per SHRC policy)*

❑ Yes ❑ No ❑ N/A If no, please explain: _____

E.3 Number of SRHC Serious Unexpected Events: _____.

In the opinion of the Investigator, is there a trend in the Serious Unexpected Events? ❑ Yes ❑ No

If yes, please explain: _____

E.4 Have all SRHC Serious Unexpected Events been reported to the SRHC REB:

❑ Yes ❑ No ❑ N/A If no, please explain: _____

F. Attestation

My signature below confirms that the information on this report is true and accurate to the best of my knowledge, and that I have reported all reportable deviations in accordance with SRHC procedures and reported all serious unexpected adverse events involving Southlake patients to the SRHC REB. I am not aware of any new information that may affect the continuation or safety of this study for participants.

Name of Local Qualified Investigator: _____

Signature of Local Qualified Investigator: _____ **Date:** _____

Name of person completing this form: _____

Signature of person completing this form: _____ **Date:** _____

RETURN THIS COMPLETED FORM TO THE RESEARCH OFFICE:

Southlake Regional Health Centre Medical Arts Building, 596 Davis Drive, Suite 512 Newmarket, Ontario L3Y 2P9

Phone: 905-895-4521 ext. 2763 Fax: 905-952-3068 Email: REBsubmissions@southlakeregional.org

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