

Research Ethics Office
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St. Michael's
Inspired Care.
Inspiring Science.

January 23, 2018

Dr. Norman Marcon,
Department of Medicine, Division of Gastroenterology,
St Michael's Hospital

Dear Dr. Marcon,

Re: REB# 08-265 - Barrett's Esophagus Database

REB APPROVAL:	Original Approval Date	December 19, 2008
	Annual/Interval Review Date	December 19, 2018

Thank you for your communications dated January 25, 2017 (received December 01, 2017) regarding the above named study.

I have reviewed and hereby issue St. Michael's Hospital (SMH) Research Ethics Board (REB) approval for:

1. Amendment – Increase enrollment to 300 participants per year
2. Protocol – ver: January 2017

Please note that no member of the St. Michael's Hospital Research Ethics Board associated with this submission was involved in its deliberation, review or approval.

During the course of this investigation, any significant deviations from the approved protocol and/or unanticipated developments or significant adverse events should immediately be brought to the attention of the REB. Furthermore, it should be acknowledged that shared electronic health systems such as ConnectingOntario, PRO, RM&R, OLIS, HDIRS, eCHN, DPV, and IAR do not permit access for research purposes.

For studies which are registered on a publicly available Clinical Trials registry (e.g. ClinicalTrials.gov), please ensure the record is updated to accurately reflect the status of the study.

The St. Michael's Hospital (SMH) Research Ethics Board (REB) operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans, the Ontario Personal Health Information Protection Act, 2004, and ICH Good Clinical Practice Consolidated Guideline E6, Health Canada Part C Division 5 of the Food and Drug Regulations, Part 4 of the Natural Health Product Regulations, and the Medical Devices regulations. Furthermore, all investigational drug trials at SMH are conducted by Qualified Investigators (as defined in the latter document).

Good luck with your investigations.

With best wishes

☐ David Mazer, MD
Chair, Research Ethics Board
DM/PB/MS/ac

☒ Philip Berger, MD
Vice Chair, Research Ethics Board

☐ Michael Szego, PhD
Vice Chair, Research Ethics Board

Dr. Norman Marcon (REB# 08-265)