St. Michael's
Inspired Care.
Inspiring Science.

[redacted]

Patient ID
[redacted]

Consent to Surgery, Diagnostic Procedure or Treatment

Form I

I. INFORMING PATIENT ABOUT PROCEDURE / TREATMENT:

A. To be completed by the Health Practitioner Proposing the Treatment

(N.B. Failure to complete this portion of the consent form may result in the withholding of treatment to this patient.)

1. I confirm that I have personally explained the anticipated effects, the nature, the material risk, and special or unusual risks and side effects and alternative courses of action of the proposed procedure / treatment as follows:

[redacted]

2. I have afforded [redacted] an opportunity to ask questions which I have answered.
(Print Name of Patient or Substitute Decision Maker (SDM))

Signature [redacted] Print Name Legibly [redacted] Date 4/14/2017

II. VERIFICATION OF INFORMED CONSENT BY PATIENT OR SUBSTITUTE DECISION MAKER:

1. I confirm that the nature, material side effects, material risk, special or unusual risks and alternative courses of action, as well as the consequences of not having the treatment, have been explained to me by [redacted]
(Print Name & Title of Health Practitioner)

2. I confirm that I understand and am satisfied with the explanations about the nature, effects, risks and side effects of the treatment(s) / procedure(s) that will be performed on me, and I confirm that I have been afforded an opportunity to ask questions about these matters and my questions have been answered to my satisfaction.

3. I understand that St. Michael's Hospital is a teaching hospital which means that various medical care personnel and/or student health care providers (i.e., students, interns, residents) may be involved in certain aspects of the procedure / treatment and throughout my hospital stay under close supervision - either in an educational or therapeutic role.

4. I agree that tissue removed for diagnostic or therapeutic purposes may be disposed of, stored or used afterwards for education and/or scientific research.

I, [redacted] hereby consent to the proposed surgery, diagnostic procedure and/or treatment described above (including all preliminary and related procedures, the administration of general and/or other anaesthetics, and such additional or alternative procedures as may become necessary during the course of the diagnostic procedure and/or treatment).

[redacted] 4/14/2017

Signature of Patient / Substitute Decision Maker (If patient is U.S. or other foreign resident, Form III must be completed) — Date

Signature of Substitute Decision Maker / Relationship to Patient (Please print) — Date

Signature of Witness to signature — Name & Title of Witness (Please print)

Where an Interpreter is involved:

Signature of Interpreter — Name of Interpreter (Please print) — Date

Division of Gastroenterology,
30 Bond Street, Toronto, ON M5B 1W8
Phone: (416) 864-6060 ext 2965; Fax: (416) 864-5449
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Principal Investigator: Dr Norman Marcon
Co-Investigators: Dr Paul Kortan, Dr Gabor Kandel, Dr Gary May

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Serving with Compassion

ST. MICHAEL'S HOSPITAL
A teaching hospital affiliated with the University of Toronto

CONSENT TO BE INCLUDED IN ST. MICHAEL'S HOSPITAL BARRETT'S ESOPHAGUS DATABASE

You are being asked to consider agreeing to have your personal health information relevant to your Barrett's Esophagus (BE) placed in the St. Michael's Hospital Barrett's Esophagus Database, and to be contacted in the future for research studies related to BE. If you agree to this, you would be allowing the principal investigator and co-investigators as indicated above (study doctors) and their research study staff access to information in your doctor's clinical notes, such as demographics, age, sex, occupation, past medical history, family history, clinical history, physical examination observations and results of any of your clinical investigations, for the purpose of placing the required information in the BE Database. Before agreeing to take part in this study database, it is important that you read the information in this consent form. You should not sign this consent form until you are sure you understand the information. Participation in this study database is voluntary. If you have any questions, ask a study doctor or study staff. You may also wish to discuss your participation in this database with your family doctor, a family member or close friend.

What is the Barrett's Esophagus Database?
The Barrett's Esophagus Database is a compilation of coded personal health information relevant to BE, of patients who have been assessed for BE at St. Michael's Hospital, for whom this information can be collected. As it is coded, the information in the database will not contain personally identifiable information about you, such as your name and medical record number. That information collected will be securely stored in a separate file that only the study doctors and study staff can access and link to the database.

What is the Purpose of this Database?
The principal investigator and co-investigators as indicated above (study doctors) at St. Michael's Hospital are involved in research studies in BE. The purpose of the BE database is to allow these study doctors to select potential candidates for research studies related to BE and also to collect and analyze information to better understand this disease. The database is confidential and will only be used by these study doctors at St. Michael's Hospital and their research study staff for the purposes as stated and possibly the St. Michael's Hospital Research Ethics Board, who may see the BE database (and also the personally identifiable information collected about you) for the purpose of monitoring. Your information will not be given to anyone else, including other doctors, drug companies, insurance companies or government agencies, unless it is required by law. In no way does signing this consent form waive your legal rights nor release the study doctors or involved institution from their legal and professional responsibilities.

What are the potential risks and potential benefits of being included in this Database?
The only foreseeable risk of being included in this database would be if your information was unintentionally released. The study doctors will protect your information to the greatest extent possible. The chance that this information will accidentally be released is small. You may receive no direct benefits from being in this study database, but you may be contacted if there is a research study related to BE that you might qualify to participate in, and your information along with the other information in the database may be used to further medical or scientific knowledge about BE.

What if I do not want to be in the BE Database or have questions about the BE Database?
Participation in this study database is entirely voluntary. If you do not want to be in the BE database, you simply tell the study doctor or study research coordinator that you do not want to be included and you do not sign this consent form. This will not have any impact on your or your family's customary care at St. Michael's Hospital. If you have any questions about the BE database, or if you want to withdraw your information from the database at any time – you may call Dr. Marcon at 416-864-3092 or the Gastrointestinal (GI) Research office at 416-864-6060 ext 2965. If you withdraw your information from the database, this will not have any impact on your or your family's customary care at St. Michael's Hospital.

Research Ethics Board Contact:
If you have any questions about your rights as a research participant, contact the Chair of St. Michael's Hospital Research Ethics Board at 416-864-6060 Ext 2557, during business hours.

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Participation in the BE database has been explained to me, and my questions have been answered to my satisfaction. I understand that I may be contacted by the research study staff or study doctors regarding future participation in research studies related to BE, and that I may accept or decline such requests without affecting the quality of medical care at St. Michael's Hospital for me and for other members of my family. Also, I have the right not to participate in the BE Database and the right to withdraw from participation in the BE Database without affecting the quality of medical care at St. Michael's Hospital for me and for other members of my family. As well, the potential risks and benefits of participating have been explained to me.

I have been told that I have not waived my legal rights nor released the study doctors or involved institution from their legal and professional responsibilities. I know that I may ask now, or in the future, any questions I have about my participation in the BE Database. I have been told that information on the database relating to me and my care will be kept confidential and that no information will be disclosed without my permission unless required by law. I have been given sufficient time to read the information in this consent form.

I consent to be included in the BE database. I will be given a signed copy of this consent form.

[redacted] 4/14/2017

Printed name of participant **Signature and date**

[redacted] [redacted]

Printed name and position of person conducting consent discussion