Informed Consent Form for Participation in a Research Study

Study Title: An integrated strategy for the expedited diagnosis, referral, assessment and treatment of complex colorectal polyps

Sponsor/Funder(s): Division of Gastroenterology, St. Michael's Hospital

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INTRODUCTION

You are being invited to consider participating in a research study. You are invited to participate in this study because you were found to have a large or complex polyp during your colonoscopy and your doctor has referred your case to the expert Therapeutic Endoscopy group at St. Michael's Hospital. A polyp is a small clump of cells on the inside surface of your colon. This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

Please take your time in making your decision. You may find it helpful to discuss it with your friends and family.

Taking part in this study is voluntary. You have the option to not participate at all or you may choose to leave the study at any time. Deciding not to take part or deciding to leave the study later will not result in any penalty or affect current or future health care for you or your family.

IS THERE A CONFLICT OF INTEREST?

There are no conflicts of interest to declare related to this study.

WHY IS THIS STUDY BEING DONE?

Colonoscopy may prevent colon cancer through the removal of pre-cancerous polyps. While most polyps can be removed with relative ease by most practitioners of colonoscopy, approximately 5% of polyps may be too large or complex and require referral to specialized centers such as St. Michael's Hospital (SMH). We have a long track record of successful treatment of large polyps by a procedure called endoscopic mucosal resection (EMR), which allows us to remove these pre-cancerous growths during colonoscopy. The EMR procedure is routine and proven to be the best and safest way of removing large polyps. However, we are conducting research to monitor outcomes of your procedure to help us learn how the process may be improved. We will keep this data confidential and it will be used by the research staff at St. Michael's Hospital only for this purpose. The St. Michael's Hospital Research Ethics Board may see the data to ensure that the study is being conducted appropriately. The analyzed information may be shared with other doctors who are collecting similar information. You will be identified in the database by number only. The information will not be shared with any other party 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 OTHER CHOICES ARE THERE?

Participation in this study is voluntary. If you choose not to participate in the research study you will continue to receive the same colonoscopy and EMR procedure that is the standard of care. If you do not want your information to be included in the database, simply tell the study doctor or study research coordinator that you do not want to be included and do not sign this consent form.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 400 people will take part in this study. This study should take 2 years to complete and the results should be known in about *3* years.

WHAT WILL HAPPEN DURING THIS STUDY?

You are scheduled for a colonoscopy to remove a large colon polyp. Your doctor has discussed the procedure with you. This database is a compilation of information about patients who undergo the removal of a large polyp by the EMR method. We would collect data about your initial procedure and any subsequent follow-up as it relates to your colon polyp for approximately 6 months.

The research coordinator will contact you by telephone to explain the study and discuss what is involved. If you need more information, you can meet with the coordinator in person, or may be booked with one of the attending physicians in pre-procedure consultation. Before any tests or procedures are performed, you will be asked to review and sign this consent form. A copy of this signed and dated consent form will be given to you.

When coming for colonoscopy for polyp removal, all patients are asked to arrive 1 hour prior to the scheduled procedure time. Upon arrival to the endoscopy unit, the research coordinator will meet with you to discuss the study and have you sign this form. This may take around 20 minutes. You will then meet the doctor who will perform the colonoscopy. They will discuss the clinical risks and benefits of the procedure and obtain your permission to proceed, including signing of the hospital's clinical consent form. Some of this information will already be collected in your health record as part of your standard of care.

- Your basic demographics (age, gender)
- Medical history. Your study doctor or his/her staff will ask you questions about your medical history and what medications you are taking.
- Information about the polyp, including the photographs and the video of it provided by the doctor who referred you for the procedure
- If you had previous colonoscopies we will review the data about the procedures and wait times you experienced

Colonoscopy and polyp removal will be performed using standard methods at the discretion of the treating doctor. You will receive standard doses of conscious sedation medications during your procedure.
Post procedure care will remain unchanged from usual clinical standard-of-care.

Follow up

The research coordinator will contact you by telephone 2-4 weeks after the procedure to follow up. At the follow-up you will be asked about medication you are taking and your overall health. If you were in the hospital since your procedure, you will be asked to provide all information about any subsequent procedures and/or hospital stays. This will allow the Study Doctor to determine how you are doing following your procedure. All follow-up contact will take approximately 15 minutes of your time.
As per standard clinical care, you will have a repeat colonoscopy in 6 months to make sure that the entire polyp was successfully removed and that the pre-cancerous growth has been effectively cured. We will collect data about this procedure.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

If you choose to participate in this study, you will be expected to:

- Tell the study doctor about your current medical conditions;

- Tell the study doctor if you are currently participating in another research study
- Report changes in health

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

Your involvement in the research study will consist of the telephone screening session; the colonoscopy procedure day, the telephone follow up conducted 2-4 weeks after the colonoscopy and the surveillance colonoscopy procedure performed approximately 6 months later.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. If you choose to withdraw from the study, you are encouraged to contact the research team.

Beginning on the date that you withdraw your approval, no new personal health information will be used for research. However, the study doctor/investigator may continue to use the health information that was provided before you withdrew your approval.

If you do decide to stop participating, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

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.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

You will receive no benefit from participating in this study. Results from this study will be used to assist physicians in improving patient care of future patients with regard to clinical outcomes, and patient quality of life

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

All persons involved in the study, including the study investigators, coordinators, nurses and delegates (hereby referred to as “study staff”) are committed to respecting your privacy. No other persons will have access to your personal health information without your consent, unless required by law. The study staff will make every effort to keep your personal health information private and confidential in accordance with all applicable privacy legislations, including the Personal Health Information Protection Act (PHIPA) of Ontario. The study staff will need access to the following personal identifying information for research purposes: name, medical record number, month and year of birth, and telephone numbers. Any health information recorded for study purposes will be “de-identified” by replacing your personal identifying information with a “study number”. The study staff at St. Michael’s Hospital is in control of the study code key, which is needed to connect your study number to you personally. The link between the study number and your personal identity will be safeguarded by the St. Michael’s Hospital study staff. It is important to understand that despite these protections being in place, there continues to be the risk of unintentional release of information. The principal investigator will protect your records and keep all the information in your study file confidential to the greatest extent possible. The chance that this information will be accidentally released is small. Paper copies will be stored in

the cabinet in the research coordinator's office. Access to the office is restricted to research staff. Electronic copies of the data will be stored in the password-protected folder on the St. Michael's Hospital server. This folder will be accessible only to research staff.

Authorized representatives of the following organizations may look at your original (identifiable) medical/clinical records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

- Division of Gastroenterology, St. Michael's Hospital, the Sponsor of this study
- The research ethics board who oversees the ethical conduct of this study in Ontario
- This institution to oversee the conduct of research at this location

Information collected about you for the study (called study data) may also be sent to the organizations listed above. Representatives of Clinical Trials Ontario, a not-for-profit organization, may see study data that is sent to the research ethics board for this study. Your name, address, email, or other information that may directly identify you will not be used. The records received by these organizations may contain your disclose identifiers e.g., participant code, sex, partial date of birth and age.

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be used in analyses and will be published and presented to the scientific community at meetings and in journals.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

A copy of the consent form that you sign to enter the study may be included in your health record/hospital chart.

WILL FAMILY DOCTORS/HEALTH CARE PROVIDERS KNOW WHO IS PARTICIPATING IN THIS STUDY?

Your family doctor/health care provider may be informed that you are taking part in a study so that you can be provided with appropriate medical care. If you do not want your family doctor/health care provider to be informed, please discuss this with the study team.

WHAT IS THE COST TO PARTICIPANTS?

Participation in this study will not involve any additional costs to you or your private health care insurance.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

You will not be paid for taking part in this study.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results of this study, please let the study doctor know. Your rights to privacy are legally protected by federal and provincial laws that require

safeguards to ensure that your privacy is respected.

By signing this form you do not give up any of your legal rights against the study doctor, sponsor or involved institutions for compensation, nor does this form relieve the study doctor, sponsor or their agents of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in this study.

WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT A RESEARCH PARTICIPANT?

During the study, the researchers may learn something about you that they did not expect. For example, the researchers may find out that you have another medical condition.

If during the research study the study doctor learns that you have a medical condition that was unknown, with your consent, we will communicate all medically actionable incidental research findings to you. You will be offered the same treatment and care as if you were not in the research study

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, or if you suffer a research-related injury, you can talk to the research team, or the person who is in charge of the study at this institution. That person is:

_____	_____
Name	Telephone

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. That person is:

Unity Health Toronto Research Ethics Board	416-864-6060 Ext. 2557
Name	Telephone

SIGNATURES

- All of my questions have been answered,
- I understand the information within this informed consent form,
- I allow access to medical records and related personal health information as explained in this consent form,
- I do not give up any of my legal rights by signing this consent form,
- I understand that my family doctor/health care provider will be informed of study participation
- I agree to take part in this study.

Signature of Participant	PRINTED NAME	Date and Time

Signature of Person Conducting the Consent Discussion	PRINTED NAME & ROLE	Date and Time