Supplementary File 3 – Patient consent form

Introduction:

You are being invited to be a research participant. This research is designed to investigate the use of a supportive intervention on patient-reported outcomes in patients who have undergone surgery for rectal cancer. You have the right to know about the purpose and procedures that are to be used in this research study, and to be informed about the potential benefits and risks of this research.

Before you agree to take part in this study, it is important that you read the information in this consent form. You should ask as many questions as you need to in order to understand what you will be asked to do. You do not have to take part in this study if you do not want to.

The Medical/Biomedical (MBM) Research Ethics Committee of the Centre intégré universitaire de santé et de services sociaux of West Central Montreal Health (CIUSSS WCMH) has approved and is responsible for the continuing ethical oversight of the study at the Jewish General Hospital.

Goals and Objectives:

After surgery for rectal cancer, many patients suffer from Low Anterior Resection Syndrome (LARS), which includes a variety of negative bowel-related symptoms as a consequence of removing the rectum. LARS can negatively impact quality of life. **The goal of this study is to evaluate the impact of a supportive intervention for LARS, with the hopes that it will improve various outcomes in patient care after surgery.** Specifically, to identify whether our supportive intervention focusing on LARS can:

- improve the quality of life among patients undergoing surgery for rectal cancer
- increase patient engagement in their own healthcare, as measured by the "Patient Activation Measure" (a questionnaire designed at evaluating the patient's knowledge, skills, and confidence in care for their own health)
- improve bowel symptoms
- decrease emotional distress

Procedures:

- We are inviting all patients who underwent a Low Anterior Resection to remove a tumor in the rectum and who had a temporary ostomy ("bag"), and who are now scheduled to have their ostomy closure operation (the "reconnection" operation).
- As part of the study, we will access your medical chart from the hospital and collect some important information regarding your rectal cancer operation, as part of the research.
- You will then be randomly assigned to either the supportive intervention group or the control group (no supportive intervention), meaning that you will have a 50/50 chance of receiving the LARS education
- The **supportive intervention group** will receive two resources to help them manage their LARS:
  1) Educational booklet

2) Specialized nursing care

- The **control group** will **not** have access to the two resources listed above. That does not mean that control group participants shouldn't be counseled on LARS. These participants will have access to any resources that are normally available at their hospital. This may include discussions with their colorectal surgeon in the office, appointments with a nurse, and any pamphlets or online resources that your doctor might normally recommend.

Participants in the intervention group

Educational Booklet

- Participants in the intervention group will have access to an educational booklet.
- This educational booklet offers all of the essential information on LARS, including tips and tricks on how to best manage LARS at home.
- It also offers special diaries for various aspects of treatment, where participants can be expected to write down different things that did, or did not, work for their LARS. This will help reinforce positive behaviors that have helped.

Specialized nursing care

- Participants in the intervention group will have access to a specialized nurse with many years of experience caring for rectal cancer patients. The nurse will speak with participants once before their surgery and walk them through the educational booklet.
- After surgery, the nurse will call participants 5 more times during the first 12 months – at 1 month, 3 months, 6 months, 9 months, and 12 months – to answer any questions, and review the diaries.
- Lastly, the nurse will have "office hours" once a week, where she will be available by telephone or by email to answer more urgent questions.
- It is important to remember that the role of this nurse is only to help with LARS care, and she does not replace a doctor for more urgent medical issues. The nurse will use her years of experience and professional judgment to decide what sort of issues might fall outside of her role.

Participants in both groups

- Participants in both the intervention and control groups will receive several questionnaires, which will allow us to understand if the supportive intervention is helping patients with their LARS.
- **Questionnaires** will be sent out once before surgery, and then 4 more times after surgery – **at 1 month, 3 months, 6 months, and 12 months.**
- Questionnaires can either be mailed to you, sent by email, or answered over the phone – whichever you prefer. If you choose to have the questionnaires mailed to you we will include an envelope and postage so that you can send back the completed questionnaires.
- You may receive telephone calls from our research coordinator to ensure that you have received the questionnaires.

Duration

All participants, whether part of the intervention group or control group, will be followed for the first 12 months after their surgery. The first questionnaire is to be completed just prior to surgery, and the final questionnaire 12 months after surgery. After the 12 months have passed, we will not contact you for any other reasons related to the study.

Reimbursements

Participants will receive $10 for each set of completed questionnaires, and $20 once all questionnaires are completed. The 10$ gift for each completed set of questionnaires will be sent to participants as soon as the completed questionnaire is received by the research team.

Risks, Discomforts and Side-Effects:

By taking part in this study, you should be at no increased risk for unwanted side-effects or discomfort. No new medication is being recommended for the purpose of the study. All of the treatment strategies recommended in the educational booklet and by the specialized nurse are considered "standard" treatments, and are usually already discussed by the treating surgeon. If any of the questions make you uncomfortable you may choose not to answer them, or, if you become upset you may contact the PI, the nurse or any member of the research team.

Benefits:

If you are part of the supportive intervention group, we hope (and anticipate) that your knowledge regarding LARS will increase, and that you might be more active in the care of your LARS. Because of this, you may experience improvements in your quality of life and even in the severity if your LARS symptoms. If you are part of the control group, you will be less likely to get any benefit, as you are acting as a comparison group to see if our intervention is making a difference. At the end of the study, regardless of the findings, we will make our educational booklet publicly available to all participants.
That being said, we cannot guarantee that you will receive any direct benefits from this study.

Voluntary participation/withdrawal:

Your participation in this research project is voluntary. Therefore, you may refuse to participate. You may also withdraw from the study at any time, without giving any reason.

Your decision not to participate in the study, or to withdraw from it, will have no impact on the quality of care and services to which you are otherwise entitled, or on your relationship with the doctor in charge of this research study or the clinical team.

If you withdraw or are withdrawn from the study, the information collected during the study will nonetheless be stored, analyzed or used to protect the scientific integrity of the research project.

Unexpected discoveries

Any new findings that could influence your decision to stay in the research project will be shared with you as soon as possible. If this happens, we will contact you to set up a visit with your treating surgeon or oncologist. This physician will share this information with you and plan your subsequent management.

Confidentiality:

While you take part in this research study, the researcher in charge and study staff will collect and store personal identifiable information about you in a file for the purpose of the research study. Only information necessary for the research study will be collected.

All the information collected about you during the study will remain confidential within the limits of the Law. To protect your identity, your name and identifying information will be replaced with a code number that has no identifying information. The code will be linked to your hospital ID and the link between the code and your identity will be held by the researcher in charge of the study. No information that discloses your identity will be allowed to leave the institution. Your study information will be kept in a de-identified manner for 10 years by the researcher in charge of the study, after which it will be anonymized. The data will be held in a password protected file and a password protected computer in locked offices at the Jewish General Hospital. After 10 years, the anonymized data will be kept indefinitely by the Investigator for the purposes of future research in colorectal surgery After 10 years, the consent forms will be shredded in the confidential bin provided by the CIUSSS du Centre-Ouest-de-L'ile-de-Montreal.

The study information may also be used for other reasons related to the study or to help in the development of future studies.

The study information could be printed/published in medical journals or shared with other people at scientific meetings, but your identity will not be revealed.

For monitoring, control and protection purposes, your research study file as well as your medical file could be checked by a person authorized by the Research Ethics Committee of the CIUSSS du Centre-Ouest-de-l'ile de Montreal or by persons mandated by authorized public agencies. These persons are bound by a confidentiality agreement.

For safety purposes, and in order to communicate information that is required in order to protect your well-being, the principal researcher of this study will keep separate from the research documents your personal information including your name, contact information, the date your participation in the study began and when it ended for the period of ten years after the end of the study. The data will be kept in a de-identified manner for 10 years following study completion and then it will be anonymized for use in future studies on colorectal surgery. After 10 years, the consent forms will be shredded in the confidential bin provided by the CIUSSS du Centre-Ouest-de-L'ile-de-Montreal.

You have the right to look at your study file in order to check the information gathered about you and to correct it, if necessary, as long as the study researcher or the institution keeps this

information. However, you may only have access to certain information once the study has ended so that the quality of the research study is protected.

Should you suffer any harm:

By agreeing to participate in this research study, you do not give up any of your legal rights nor discharging the doctor in charge of this research study or the institution of their civil and professional responsibilities.

Investigator Compensation

The researcher in charge of this study has been awarded funding from a various professional medical societies and research granting agencies, to help cover the cost of running the study. The funds have been deposited into a research and development account.

Contact information or questions:

If you have any questions regarding the study, you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

Dr. Marylise Boutros, Primary Investigator
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For all questions regarding your rights as a research participant for this study, or if you have comments or wish to make a complaint, you may contact the Local Commissioner of Complaints and Quality of Services of the CIUSSS du Centre-Ouest-de-l'ile-de-Montreal at 514-340-8222 ext. 24222.

STATEMENT OF CONSENT
Impact of a Patient-Centered Program for Low Anterior Resection Syndrome

I have reviewed the information and consent form. Both the research study and the information contained in the consent form were explained to me. All my questions were answered, and I was given sufficient time to make a decision. After reflection, I consent to participate in this research study in accordance with the conditions stated above.
I authorize the research study team to have access to my medical record and biopsy results for the purposes of this study. I do not give up any of my legal rights by signing this consent form.

I agree to be re-contacted by the study team in the future regarding further participation in this study or to be asked about participation in other studies. Agreeing to be re-contacted does not mean I have to participate in these other studies.

YES NO INITIALS ☐

Name of the Participant Signature

Date

Consent form administered and explained in person by:

Name of the person obtaining consent Signature

Date

I certify that this information and consent form were explained to the research participant, and that the questions the participant had were answered. I undertake, together with the research team, to respect what was agreed upon in the information and consent form, and to give a signed and dated copy of this form to the research participant.

Name of the Investigator
Signature Date