THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

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INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Accelerated Enhanced RECOVERy following Minimally Invasive colorectal cancer surgery (RecoverMI)
2015-0583

Study Chair: George Chang

1. _____ _____
Participant's Name Medical Record Number

You are being asked to take part in this clinical research study at The University of Texas MD Anderson Cancer Center ("MD Anderson"). This consent and authorization form explains why this research study is being done and what your role will be if you choose to take part. This form also describes the possible risks connected with being in this study. After reviewing this information with the person responsible for your enrollment, you should know enough to be able to make an informed decision on whether you want to take part in the study.

You are being asked to take part in this study because you have colorectal cancer that will be treated with minimally invasive surgery (surgery designed to have a smaller impact on you).

2. PURPOSE OF STUDY

The goal of this clinical research study is to learn if RecoverMI care can help to shorten the time that patients are in the hospital after surgery and if it can help them recover sooner.

RecoverMI includes the following parts:

- education before surgery about the procedure and steps in your recovery
- early drinking and eating after surgery
- early activity such as walking from your bed to a chair or farther
- video-conferencing from home with the surgical team (such as using FaceTime on an iPad)

3. DESCRIPTION OF STUDY

Baseline Questionnaires and Screening
If you agree to be screened for this study, before your surgery you will complete questionnaires about your levels of anxiety and depression (if any), the location and amount of your pain (if any), and your quality of life. Completing the questionnaires should take about 5 minutes.

Signing this consent form does not mean that you will be able to take part in this study. If you agree to take part in this study, the doctor will decide if you are eligible after your surgery is completed. If you are not eligible to take part in the study, you will not be enrolled.

Study Groups
If you are found to be eligible to take part in this study, you will be randomly assigned (as in the flip of a coin) to 1 of 2 study groups. This is done because no one knows if one group is the same, better, or worse than the other group.

- If you are assigned to **Group 1**, you will receive routine care after your surgery.
- If you are assigned to **Group 2**, you will receive routine care after surgery, but you will also receive RecoverMI, which has some changes from routine care as described below. You will be loaned an iPad to use for video-conferencing in this study.

Study Visits (Group 1)
Once you are about to leave the hospital after surgery, you will complete the pain and quality-of-life questionnaires again.

Study Visits (Group 2)
You will be able to leave the hospital once the doctor thinks you are ready. This will involve the usual requirements for leaving. However, unlike Group 1, who needs to be able to tolerate both liquids and solids by mouth, you will only need to be able to tolerate liquids without nausea. Also, unlike Group 1, you will not need to have bowel function (having gas or a bowel movement).

On the day you are able to leave the hospital, which may be the day after surgery:

- You will complete the pain and quality-of-life questionnaires.
- If the doctor thinks it is needed, you will receive fluids by vein over 1-2 hours to help you stay hydrated.

On Day 2 after surgery, you will use your RecoverMI device to have a video conference call with the surgical team in the morning. If the surgical team thinks it is needed, you will have a follow-up video conference call with them that afternoon or evening. In both calls, you will be asked how you are doing. These calls should take about 10 minutes.

To help keep track of how well hydrated you are at home, you will fill out a diary of how much you urinate each day. The surgical team will talk to you about your diary on Day 2 after surgery and will tell you if you need to keep using it after that. If they think it is needed, you will come to the clinic to receive fluids by vein over 1-2 hours on Days 2 and/or 3 after surgery.

Length of Participation
You will be on study until your Day 30 follow-up call. You will be taken off study early if there are certain changes in your surgical plan, if the doctor thinks it is in your best interest, or if you are unable to follow study directions.

Follow-up
At your routine visit within 14 days after surgery, you will complete the pain and quality-of-life questionnaires. Group 2 participants will return the iPad to the clinic.

At 30 days after your surgery, the study staff will call you to check on your health and how you are recovering. You will also complete the anxiety/depression, pain, and quality-of life questionnaires as well as a new questionnaire that asks how satisfied you were with your surgical care. Completing these questionnaires should take about 10-20 minutes. You will receive these questionnaires with a self-addressed return envelope at your visit 14 days after surgery and then hold onto them until this phone call. You will mail the questionnaires back to the clinic after the phone call.

This is an investigational study. The study doctor can explain how RecoverMI is designed to work.

You and/or your insurance provider will be responsible for the cost of the surgery, fluids, and follow-up care.

If you are in Group 2, there will be no added cost to you for the video teleconferencing. If you need a data plan to use the iPad, you will receive a data plan at no cost to you during the time you need to use the iPad for the study.

Up to 32 participants will be enrolled in this study. All will take part at MD Anderson.

4. RISKS, SIDE EFFECTS, AND DISCOMFORTS TO PARTICIPANTS

While on this study, you are at risk for side effects. You should discuss these with the study doctor. The known side effects are listed in this form, but they will vary from person to person.

If you are in Group 2, you have a higher risk that the possible surgical side effects of nausea, abdominal swelling, and vomiting may occur at home, since you will leave the hospital earlier. If these side effects happen before you leave the hospital, the side effects will be treated before you are able to leave the hospital, which may cause a delay in going home.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaires, you are encouraged to contact your doctor or the study chair.

Once you return the iPad, all data that is stored on it will be deleted. If the iPad is stolen or damaged, you will not have to pay for it. However, you must file a police report right away and all data will be deleted remotely. If you use more than the provided amount of data, you will be responsible for the cost of any fees for too much data usage.

This study may involve unpredictable risks to the participants.

5. POTENTIAL BENEFITS

If you are in Group 2, RecoverMI may help to shorten the total time period when you are in the hospital right after surgery. It may decrease the chance that you have to go back to the hospital again while recovering from surgery. Future patients may benefit from what is learned. There may be no benefits for you in this study.

6. ALTERNATIVE PROCEDURES OR TREATMENTS

You may choose not to take part in this study.

Additional Information

7. You may ask the study chair any questions you have about this study. You may contact the study chair, Dr. George Chang, at 713-563-1875. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-2933 with any questions that have to do with this study or your rights as a study participant.

8. Your participation in this research study is strictly voluntary. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson.

9. This study or your participation in it may be changed or stopped at any time by the study chair, American Society of Colon and Rectal Surgeons, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP - a regulatory agency that oversees research in humans), or the IRB of MD Anderson.

10. You will be informed of any new findings that might affect your willingness to continue taking part in the study.

11. MD Anderson may benefit from your participation and/or what is learned in this study.

12. This study is supported by: American Society of Colon and Rectal Surgeons.

STUDY COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson or American Society of Colon and Rectal Surgeons for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-2933 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs, including hospitalization, nausea, vomiting, low blood cell counts, and dehydration. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary

manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

Your parking will be validated for unplanned outpatient visits related to your taking part in the study, and occurring before your first follow-up visit.

Authorization for Use and Disclosure of Protected Health Information:

A. During the course of this study, the research team at MD Anderson will be collecting and using your protected health information. This information may include personal identifying information about you (such as your name, race, date of birth, gender, city, and zip code), your medical history, study schedule, and the results of any of your tests, therapies, and/or procedures. The purpose of collecting and sharing this information is to learn about how the study procedures may affect the disease and any study-related side effects. Your doctor and the research team may share your study information with the parties named in Section D below.

B. Signing this consent and authorization form is optional. However, if you refuse to provide your authorization to use and disclose your protected health information for this study, you will not be able to participate in this research project.

C. MD Anderson will take appropriate steps to keep your protected health information private when possible, and it will be protected according to state and federal law. However, there is no guarantee that your information will remain confidential, and it may be re-disclosed at some point. Federal agencies (such as the FDA, OHRP, or National Cancer Institute [NCI]), American Society of Colon and Rectal Surgeons, and the IRB of MD Anderson might view or receive your record in order to collect data and/or meet legal, ethical, research, and safety-related obligations. In some situations, the FDA could be required to reveal the names of participants.

D. Your protected health information may be shared with the following parties:

- American Society of Colon and Rectal Surgeons (and/or any future sponsors of the study)
- Federal agencies that require reporting of clinical study data (such as the FDA, NCI, and OHRP)
- The IRB of MD Anderson
- Officials of MD Anderson

- Clinical study monitors who verify the accuracy of the information
- Individuals with medical backgrounds who determine the effect that the treatment procedures may have on the disease
- Individuals who put all the study information together in report form

E. There is no expiration date for the use of your protected health information. You may withdraw your authorization to share your protected health information at any time in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP). You may contact the IRB Staff at 713-792-2933 with questions about how to find the NPP. If you withdraw your authorization, you will be removed from the study, and the study chair and staff will no longer use or disclose your protected health information in connection with this study, unless the study chair or staff needs to use or disclose some of your research-related personal health information to preserve the scientific value of the study. Data collected about you up to the time you withdrew will be used and included in the data analysis. The parties listed in Section D above may use and disclose any study data that were collected before you canceled your authorization.

F. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS _____ _____

SIGNATURE OF PARTICIPANT DATE

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)

The following signature line should only be filled out when the participant does not have the capacity to legally consent to take part in the study and/or sign this document on his or her own behalf.

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS _____ _____

SIGNATURE OF LAR DATE

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS _____

RELATIONSHIP TO PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol **2015-0583**.

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS _____ _____

SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for vulnerable adult participants. If witnessing the assent of a pediatric participant, leave this line blank and sign on the witness to assent page instead.

PERSON OBTAINING CONSENT

I have discussed this clinical research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

SIGNATURE OF STUDY CHAIR
OR PERSON AUTHORIZED TO OBTAIN CONSENT

DATE

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into _____ and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

NAME OF TRANSLATOR | SIGNATURE OF TRANSLATOR | DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line below.)

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION (OTHER THAN TRANSLATOR, PARENT/GUARDIAN, OR STUDY CHAIR) | DATE