

MARQUETTE GENERAL HEALTH SYSTEM

Regional Medical Center

CONSENT TO PARTICIPATE IN AN INVESTIGATIONAL STUDY

TITLE: NSABP LTS-01 - Patient Reported Outcomes in Long Term Survivors with Colon and Rectal Cancer

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This is a research study investigating the long term outcomes in patients who were treated in the past for colon and rectal cancer. Research studies include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor or a member of the research team for more explanation.

Why have I been asked to take part in this research study?

You have been asked to take part in this study because you are a colon or rectal cancer survivor who participated in a cancer treatment research study sponsored by the National Surgical Adjuvant Breast and Bowel Project (NSABP).

Who is conducting the study?

The NSABP and the University of California, Los Angeles (UCLA) are conducting this study. This study is supported by the American Cancer Society.

Why is this research study being done?

Advances in medical treatments for colon and rectal cancer have led to increasing numbers of cancer survivors. However, little is known about survivors with these cancers. This study is being done to examine the long-term quality of life of colon and rectal cancer survivors. We want to learn from your experiences how to better prepare future cancer survivors for what to expect. We also hope to identify if there are harmful or bothersome long-term effects that could be better handled to improve patient quality of life.

How many people will take part in the study?

About 1500 to 2000 people who have participated in NSABP C-05, C-06, C-07, R-02 or R-03 research studies will be invited to participate in this study.

What will happen if I take part in this research study?

A UCLA interviewer will contact you only if you agree to take part in this research study. We would like to find out how your quality of life has been affected by your treatment for cancer and how it might have interacted with other health conditions you may have. You will be asked to complete a one-time telephone interview about your quality of life that will take about 45 to 60 minutes of your time. The interview will be conducted at your convenience by an interviewer located at UCLA. The UCLA researchers will ask questions about your physical functioning and how it relates to treatments, general health perceptions and worries, emotional well-being, social and family changes, health behaviors and other chronic illnesses, the meaning of cancer, and some background information about you. Some questions may be more sensitive or personal, such as about your bowel, bladder, and sexual functioning. If the questions you are asked make you uncomfortable, you may skip any questions you do not want to answer. If you do not answer some or all of the questions, it will not affect your taking part in the study overall.

How long will I be in the study?

If you decide to participate, you will complete a one-time telephone interview with researchers at UCLA.

Can I stop being in the study?

Yes. You can decide to stop at any time. You may skip any questions you do not want to answer.

What risks can I expect from being in the study?

You may feel uncomfortable giving personal information in a telephone interview. You may find discussing your cancer experience upsetting.

Are there benefits to taking part in the study?

There may or may not be a direct benefit to you from taking part in this study. You may feel that answering questions about your health and well-being is beneficial to you in itself. Through this study we will learn about the quality of life of colon and rectal cancer survivors. The information you provide will help us gain insight into what long-term cancer survivors experience with their health and well-being. This information could help future cancer patients.

What other choices do I have if I do not take part in this study?

Instead of choosing to be in this study, you can decide not to participate. If you choose not to participate, this will not affect your participation in the treatment trial you are being followed on.

Will my medical information be kept private?

We will do our best to make sure that the personal information in your medical and research records will be kept private. However, we cannot guarantee total privacy. Your personal

information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical and research records for research, quality assurance, and data analysis include:

- the National Surgical Adjuvant Breast and Bowel Project (NSABP);
- the University of California, Los Angeles (UCLA);
- your local Institutional Review Board (IRB), a group of people who review the research study to protect your rights; and
- government agencies, including the National Cancer Institute (NCI) or its authorized representatives, the Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), and the Canadian Health Products and Food Branch (HPFB). These agencies may review the research to see that it is being done safely and correctly.

Also, some of your personal and medical information from the NSABP cancer treatment research study that you joined 5 or more years ago (C-05, C-06, C-07, R-02, or R-03) will be shared with investigators conducting the LTS-01 study. Types of information that may be shared may include personal information such as your date of birth and contact information, the type and stage of your cancer, the treatment you received, and quality of life information (if you participated in a quality of life study).

What are the costs of taking part in this study?

There is no cost to participating. You will not be paid for taking part in this study.

COSTS AND PAYMENTS:

You understand that the NSABP Group and Marquette General Hospital furnish no funds providing medical treatment for, or financial compensation to, human subjects in the event the investigational therapy results in loss or injury. You will be responsible for the cost of emergency medical treatment provided by this institution and/or by your physician. You are also aware that the ...Group and Marquette General Hospital will not take financial responsibility for non-acute medical problems.

Lab tests (blood), x-rays and other diagnostic tests will be done frequently to check the effects of the investigational therapy. You understand that the costs of your medication and treatment may exceed what your insurance company is willing to pay, and that you will be responsible for payment. In many instances, however, all or a portion of those costs may be reimbursed by your insurance company.

Institutional Funding:

Funds are provided from the study sponsor to Marquette General Hospital on a per patient basis to help with the institution's costs of participating in this study.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

WHOM DO I CALL IF I HAVE PROBLEMS OR QUESTIONS?

In the event that physical injury occurs as a result of this research, facilities for treatment of injury will be available; however, you will not automatically be provided with reimbursement for medical care or other compensation. For more information concerning the research and research-related risks or injuries, you can notify Dr. _____, or his/her associates, who may be reached by phoning the office at (906) 225-3922. During the evenings, weekends, or holidays you may phone Marquette General Hospital at (906) 228-9440, and request to speak with the oncology physician on call. You can also call the Patient Advocate at Marquette General Hospital at (906) 228-9440, if you have any questions, comments, or concerns about the study or your rights as a research subject.

Where can I get more information?

You may call the National Cancer Institute's Cancer Information Service at:

1-800-4 CANCER (1-800-422-6237) or TTY: 1-800-332-8615

- You may also visit the NCI Web Site at <http://cancer.gov>
- For NCI's clinical trials information, go to: <http://cancer.gov/clinicaltrials>
- For NCI's general information about cancer, go to <http://cancer.gov/cancerinfo>
- You may also visit the NSABP Web site at <http://www.nsabp.pitt.edu>

You will get a copy of this form. If you want more information about this study, ask your study doctor.

Your signature below means that you have freely agreed to participate in this investigational study.

Patient's Signature

Date

Signature of person conducting
Informed consent discussion

Date

I certify that the nature and purpose, the potential benefits, and possible risks associated with participation in this research study have been explained to the patient indicated, and that any questions about this information have been answered.

Investigator's Signature

Date

Your signature below means that you do not wish to participate in this investigational study.

Patient's Signature

Date

Signature of person conducting
Informed consent discussion

Date

Investigator's Signature

Date