



INFORMED CONSENT FOR CLINICAL RESEARCH

A Prospective Study of Quality of Life in Patients with Bladder Cancer

You have been asked to participate in a research study. In order to decide whether or not you should agree to be part of this research study, you should know enough about its risks and benefits in order to make a sound judgment. This process is known as informed consent.

A member of the study staff will explain the research study to you. 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 family and friends.

This consent form gives you detailed information about the research study. Once you understand the study, its risks, and its benefits, you will be asked to sign the form if you wish to take part. You will be given a copy to keep.

Why is this study being done?

The purpose of this study is to learn about the quality of life of people living with bladder cancer. **We are interested in learning about how the treatments for bladder cancer affect people.** We plan to use the findings from this study to help doctors provide better care and information to patients with bladder cancer.

Is there a potential conflict of interest for this study?

There are no known investigator and/or institutional conflicts of interest for this study.

How was I selected to be in this study?

You are being asked to take part in this study because you are scheduled to undergo radical cystectomy (removal of the bladder) for bladder cancer at Memorial Sloan Kettering Cancer Center.

How many people will take part in the study?

About 550 people will take part in this study at MSKCC.

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

Before you begin the study ...

A Research Study Assistant will review your chart to be sure you can participate. We will check to see the type of bladder cancer you have and the treatment you are getting.



During the study...

If you choose to take part, then you will be asked to be interviewed and to fill out surveys several times over the next two years:

- There are two parts to this study. The first part is an interview that includes open ended questions about your quality of life. Second is a survey which consists of quantitative measures which can be done on your own or with a member of the research team.
- Regarding the interviews, you have the choice of taking the interview by telephone or in-person at a scheduled time when you come to the clinic. You will be asked to be interviewed five times over two years, before surgery and/or start of chemotherapy and at 6, 12, 18, and 24 months after surgery. During the interview a research staff member will ask questions about your concerns, problems and goals, and what you are doing about them. You can be interviewed in-person at the clinic when you come for an appointment, or over the phone. Each interview takes about 60 minutes.
- For the surveys, you also have the choice of filling out the paper and pencil survey on your own at home, online (when and if available) or at the clinic, or with a study staff member at the clinic or by telephone. The surveys ask about urinary and bowel problems, sexual functioning, and your recovery from surgery as well as questions about your general health, activity level and mood. The surveys are a little different each time. The first one is longer, and takes about one hour. The rest will take about 45 minutes. You will be asked to take the survey before surgery and at 3, 6, 12, 18, and 24 months after surgery.

If you need chemotherapy before surgery, we will also ask you to take the survey and the interview right after you finish the chemotherapy. That means you would complete survey and interview both prior to start of chemotherapy and then again prior surgery.

- You will be asked to answer all survey and interview on your own, without speaking to family, friends or anyone else. However, study staff will always be glad to assist you.
- If you need to take a break during a survey or interview session, that can be arranged.
- If for any reason you cannot finish a questionnaire or interview at one time, that is okay. We will schedule time to finish with you within one week.
- We will also check your medical record to more get up to date information about your treatment.

We want this study to provide the most in-depth and detailed look to date at bladder cancer patients' quality of life. For this reason, we need to ask enough questions so that patients can describe any problems they may be having in detail. We need to gather information several times over the next few years to understand how quality of life changes. People can respond to treatment in many different ways, so it is very important to get each person's point of view.

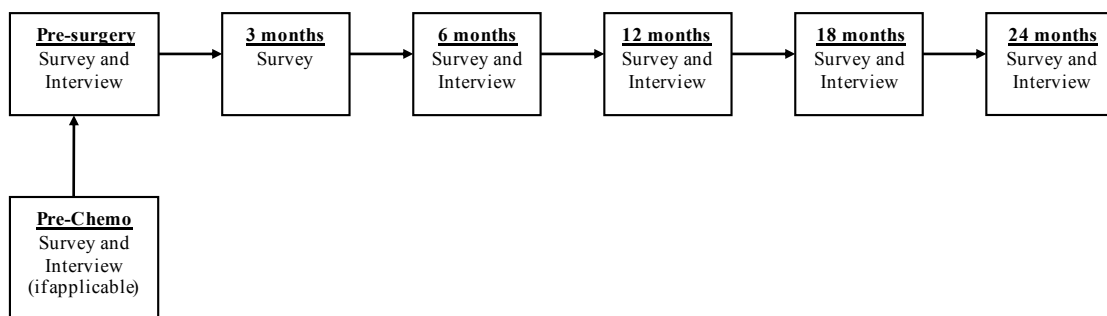


After the study...

After you are finished with the study, your doctor may ask you to return for follow-up visits. These visits are considered standard of care and will be determined by your doctor, if he/she deems it necessary.

How long will I be in the study?

You will be asked to take part in the study for about two years.



Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest; if you do not follow the study rules; or if the study is stopped.

What side effects or risks can I expect from being in the study?

There are no physical risks involved with this study. The chance that you will have any side effects is very low. There is a small risk that you may become upset by completing the survey or answering the interview about health and health problems. If any of these questions make you feel upset and you would like to discuss your feelings, a member of our staff can talk with you, or give you a referral to a medical professional if you wish.

Are there benefits to taking part in the study?

There are no direct benefits to you to being in the study.

- You may find it interesting to complete quality of life interviews, as a way of taking stock of illness and treatment concerns.



- You may also benefit from sharing your experience or from knowing that this research may help others.
- This study may allow us to identify better ways to understand changes in quality of life related to bladder cancer.

Will I receive the results from the study?

If you would like, we will send you brief reports of study findings in about 2-3 years and at the conclusion of this project. A study staff member will ask you if you would like this summary information.

Do I have to take part in this study?

The choice to take part in this study or not is yours. Make your choice based on what we have explained to you and what you have read about the study

Will my medical information be kept private?

Every effort will be made to keep your study records private. It is the responsibility of the research staff at Memorial Hospital to make sure that your records are managed to protect your privacy. If information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. Trained staff at Memorial Hospital may review your records if necessary. Access to your medical information will be limited to those listed in the Research Authorization Form, which is a part of the informed consent process.

A description of this clinical trial may be available on <http://www.ClinicalTrials.gov>. 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.

What are the costs of taking part in this study?

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

What happens if I am injured because I took part in this study?

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for the medical treatment.

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



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regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor Dr. Bernard Bochner at 646-422-4387 and/or Dr. Guido Dalbagni at 646-422-4394.

Any hospital that does research on people has an institutional review board (IRB). This board reviews all new studies to make sure that the patient's rights and welfare are protected. The IRB at MSKCC has reviewed this study.

For a non-physician whom you may call for more information about the consent process, research patients' rights, or research related injury is Jorge Capote, RN, Patient Representative, telephone number: (212) 639-8254.



RESEARCH AUTHORIZATION

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Research Participant Name: _____

Research Participant MRN: _____

Information about you and your health is personal. It is "Protected Health Information." We cannot use any of your health information for research unless you tell us that we can. If you take part in this research, the people or organizations that can look at your information are listed below. You will have to sign this form to tell us we have your permission to share your protected health information.

The following persons and/or organizations may use or disclose your information for purposes related to this research:

- The people in charge of the study and their assistants and support staff.

The following persons and/or organizations may look at your information for purposes related to this research:

- Members and staff of the hospital's Office of Clinical Research, Computing Resource Group that manages research databases, Data Safety Monitoring Board, and the Quality Assurance Committee.
- Members and staff of the hospital's Institutional Review Board and Privacy Board.
- The National Cancer Institute, National Institutes of Health, U.S. Food and Drug Administration, and other agencies responsible for oversight.
- The following sponsor(s) of this research: Memorial Sloan-Kettering Cancer Center
- Other:
 - Dr. Bruce Rapkin and his research staff at Albert Einstein College of Medicine
 - Dr. Bradley Morganstern and his research staff at North Shore LIJ Health Systems
 - Dr. Michael Feuerstein and his research staff at Lenox Hill Hospital

The following information will be used and/or disclosed for this research:

- Your entire research record.
- HIV-related information. This includes any information showing that you had an HIV-related test, have HIV infection, HIV-related illnesses or AIDS, or any information that could mean you might have been exposed to HIV. New York State requires us to obtain this consent.
- HIV-related information collected during this study if you choose to disclose it when talking to any of the staff.
- Your medical records from the hospital
- The following information: Interview and Questionnaires



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If you sign this form, it means you are giving us permission to share your protected health information. We can only share it with the people or organizations describe above. The purpose for the use and sharing of this information is to conduct this study. This signed form allows us to make sure that everyone who needs information related to this study can get it.

Your protected health information may also be used for your research treatment, to collect payment for care you receive while on the study (when applicable), and to run the business operations of the hospital.

Some of the people or organizations listed above may not be subject to privacy laws. This means they could share your information again.

You do not have to sign this form. If you do not sign it, you will not be able to take part in the study. Your health care outside the study will not be affected. The payment for your health care or your health benefits will not be affected.

You have the right to withdraw from the study at any time. If you sign this authorization form, you also have the right to withdraw it at any time. If you withdraw it, we cannot use or share anymore of your research data. If the hospital has already used or shared your information, it cannot be taken back. This authorization allows us to use your information until you say we cannot use it anymore. If you want to withdraw your authorization, write to: Bernard Bochner, MD at the Department of Surgery-Urology Service, Memorial Sloan-Kettering Cancer Center.

Notice About HIV-Related Information

Once we have shared your HIV-related information, it can only be shared again if federal or state laws allow it. You have the right to ask for a list of any people who get your HIV-related information that are not listed above. There are two agencies to help protect your rights. Call them if you think you have been singled out or harmed because of HIV-related information.

- New York State Division of Human Rights (800) 523-2437 or (212) 480-2493
- New York City Commission of Human Rights (212) 306-7450 or (212) 306-7500



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Participant Name: _____

Participant #: _____

(or place participant label here)

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Statement of professional obtaining consent

I have fully explained this clinical research study to the participant or his/her Legally Authorized Representative (LAR). In my judgment and the participant's or that of his/her Legally Authorized Representative, there was sufficient access to information, including risks and benefits to make an informed decision.

Consenting Professional Must Personally Sign & Date

Assent (Minor between the ages of 7 and less than 18): If the participant is a minor, I have obtained his/her assent to participate in the study to the best of their ability to understand.

YES

NO

N/A (Adult or Child <7)

Consenting Professional's Signature

Date:

Consenting Professional's Name (Print)

Participant's (or Legally Authorized Representative's (LAR)) statement

I have read this form with the description of the clinical research study. I have also talked it over with the consenting professional to my satisfaction. By signing below, I am agreeing to the following: (1) to voluntarily be a participant in this clinical research study (2) authorizing for the use and disclosure of my/their protected health information (data about myself) and (3) that I received a signed copy of this consent form.

Participant/LAR Must Personally Sign & Date

Participant/LAR Signature

Date:

Participant/LAR Name (Print)

LAR Relationship to Participant

Witness Signature (If Required)

Non-English Speaking Participant Witness and/or Interpreter: I declare that I am fluent in both English and participant's (or LAR) language and confirm that the consent discussion was appropriately translated for the participant (or LAR).

Other: I confirm that the consent discussion was appropriate for the participant's (or LAR's) understanding of the study.

Name of Witness: _____

Signature of Witness: _____ Date: _____

The Participant/Legally Authorized Representative Must Be Provided With A Signed Copy Of This Form.