ALBERT EINSTEIN COLLEGE OF MEDICINE OF YESHIVA UNIVERSITY
Montefiore Medical Center

Individual's Consent for Participation in Research

INTRODUCTION:

By signing this form you have voluntarily agreed to participate in a research study entitled: "Exploratory Study of the ERCC-1 Gene Expression in Colorectal Cancer Cell Lines and in Patients with Colorectal Cancer" to be carried out under the supervision of:

Principal Investigator: Sanjay Goel, M.D.

Office Address: Department of Oncology,
Montefiore Medical Center
1695 Eastchester Road
Bronx, New York 10461

Office Phone: 718-405-8404

STUDY SPECIFICS:

PURPOSE

You have been diagnosed with advanced colon or rectal cancer. The primary purpose of this research study is to determine if a particular protein in your blood will change when you receive treatment with a drug called oxaliplatin, which is used to treat your colon or rectal cancer. This protein is called ERCC-1. It is thought that the amount of this protein in your blood could influence the manner in which you respond to oxaliplatin.

We invite you to take part in a research study to test the amount of this protein in your blood both before and after you are treated with oxaliplatin. It is important that you read and be told several general principles that apply to all who take part in research studies: (a) taking part in the study is entirely voluntary; (b) personal benefit may not result from taking part in the study, but knowledge may be gained that will benefit others; (c) any significant new findings that relate to your treatment will be discussed with you; (d) you may withdraw from the study at any time without penalty or loss of any benefits to which you are otherwise entitled. The nature of the study, the risks, inconveniences, discomforts, and other important information about the study are discussed below.

OBJECTIVES

The purpose of this study is to attempt:

1. To find the effect of treatment with oxaliplatin on the level of the protein ERCC-1 in your blood.
2. To test the level of the protein in your tumor tissue before treatment with oxaliplatin
3. If medically feasible, and without having to inconvenience you, to test the level of the protein in your tumor after you have been treated with oxaliplatin.

PROCEDURES

This study will enroll upto 80 patients, until there is enough yield of protein from 40 patients to run the tests that the study is proposing. We will draw 9 tubes of blood (7 ml - approximately 1.5 teaspoons) at different time points, 1 on the day you sign the consent, 2 just prior to the oxaliplatin therapy, 2 just after the oxaliplatin therapy, 2 tubes will be drawn 2 days after you get the drug and the last set will be drawn before your next dose of oxaliplatin. If you are entering the study before a surgical procedure or before endoscopy (looking into your bowel through a tube), we ask that you consent to have us use your tissue for determining the amount of this protein. In addition, if required for regular care, you may need an additional endoscopy or surgery. If so, we ask that you give us permission to collect a small sample of your tumor from this procedure.

RISKS

Blood drawing
The research staff will take all efforts to ensure that you are not subject to extra skin pricks. The attempt will be to draw the blood at the time the nurse will initiate chemotherapy. However, even if the staff have to make extra skin punctures, the risks are minimal; with pain and redness and in extremely rare cases, infection, at the site your skin is punctured to draw the blood. However, you will be required to do routine blood tests during your chemotherapy, and the extra blood tests should not pose any additional hazards or risks.

Additional Biopsies
You may be asked to provide consent for biopsy of your cancer. This is to enable the research staff to study changes in a protein in your cancer. You will have a medication injected at the site of the tumor to protect you from the pain, and then the area will be thoroughly cleaned. However, the risks associated with this include pain, bleeding, and infection.

Genetic Testing:

You have been diagnosed with colon or rectal cancer. The primary purpose of this research study is to determine if a particular protein in your blood will change when you receive treatment with a drug called oxaliplatin, which is used to treat your colon or rectal cancer. This protein is called ERCC-1. It is thought that the amount of this protein in your blood could influence the manner in which you respond to oxaliplatin. We invite you to take part in a research study to test the amount of this protein in your blood both before and after you are treated with oxaliplatin.

You may wish to obtain professional genetic counseling prior to signing the informed consent. A genetic counselor is a person qualified to provide information about what the results of this type of test may mean to you and your family. You or your insurance company will be responsible for the cost of these services. However, the test for this gene is currently not commercially available and has no proven clinical usefulness.

We will obtain 2 tea/tablespoons of blood from your arm by a needle stick when you come to the clinic. This will only be done only one time.

FOR FUTURE RESEARCH

In addition to the research you are consenting to under this study, Dr. Sanjay Goel or other researchers at this or other institutions may wish to study the samples in future research. These samples, taken from your body, would be able to be linked back to you. At this time, the researcher does not know what the future studies will be. Your specimens may also be submitted to a tissue bank. The specimens may be kept for a long time, possibly up to 50 years. Information about you may be shared with other researchers who will keep the information confidential, as stated in this consent form. In some research using human blood or tissue, the specimens and their parts may enable researchers to develop medical tests or treatments that have commercial value. You will not receive any money that may result from any such commercial tests or treatments.

PLEASE INDICATE CONSENT WITH INITIALS

_____ I consent to have my specimens used for future research studies.

_____ I consent to have my specimens used for future research studies only for the study of _____

_____ I do not consent to have my specimens used for future research studies

BENEFITS

Participating in this study will not alter the quality of the treatment you receive. Oxaliplatin has been approved for use for patients with colon and rectal cancer. However, not all patients benefit to the same extent. It is thought that one reason for this varied benefit is the different amount of this protein ERCC-1 in the blood and tumor of the patients. Information obtained from this study may help others with cancer and could improve the care that they receive.

ALTERNATIVES

You may choose not to participate in this study and your care will remain the same irrespective of your decision.

COSTS

If it is felt that it is medically necessary for you to have a surgery or a biopsy or an endoscopy, it will be billed to your insurance. Any procedure related solely to research, which include the blood draws for assessment of the protein will not be billed to your insurance or to you.

In order to follow the status of your disease, we will request CT scans and other blood tests to be performed at regular intervals. These are considered routine tests and will only be performed if approved by your and if we can bill your insurance company.

CONFIDENTIALITY: (Who May See Your Records)

The study research records will be kept confidential and you will not be identified in any written or verbal reports. As part of this study, the researchers will review your medical records and will keep the information confidential. As this research involves a drug or device, the U.S. Food and Drug Administration (FDA) may inspect your research records and medical records. Your research records and medical records may also be inspected by members of the research team, the sponsors of this research, and other institutions who will participate in this study. These are: Albert Einstein College of Medicine of Yeshiva University, and the Montefiore Medical Center. All of these groups have been requested to maintain confidentiality. Your records may also be inspected by the human research committee(s) of the Albert Einstein College of Medicine Committee on Clinical Investigations (CCI), and the Montefiore Medical Center Institutional Review Board (IRB).

WHOM TO CONTACT FOR QUESTIONS:

If any questions arise related to this research project, or you believe you have any injury related to this study, you can call the principal investigator, Dr Sanjay Goel named at the beginning of this consent document in the introductory paragraph. You may also call the Administrator of The Albert Einstein College of Medicine Committee on Clinical Investigations at (718) 430-2253, Monday through Friday between 9 AM and 5 PM, or the IRB Research Compliance Analyst of the Montefiore Medical Center Institutional Review Board at (718) 798-0406, Monday through Friday between 9 AM and 5 PM.

INJURY COMPENSATION:

We do not expect any physical injury as a result of this research since the blood draws pose only minimal risk. If there is an injury, only immediate, essential, short-term medical treatment as determined by the participating hospital, will be available for the injury without charge to you personally. No monetary compensation will be offered. If additional treatment is required as a result of a physical injury related to the research, necessary medical treatment will be provided to you and billed to your insurance company or to you as part of your medical expenses.

TERMINATION OF THE STUDY

Your participation in this study is voluntary. Refusing to participate will involve no penalty or loss of benefits. You are free to withdraw your consent to receive treatment on this study at any time without affecting your future care. You are free to seek care from a research study doctor of your choice at any time. If you do not take part in or come off of the study, you will continue to be followed. If health conditions occur which would make your participation possibly dangerous, if other conditions occur that would make participation harmful to you or your health, or if new information is obtained that indicates that the present treatment is not in your best

interest, then your research study research study doctor may discontinue this treatment. Treatment will also be discontinued if you become pregnant.

PATIENT PROTECTION

You may contact either the investigator in charge or a member of the human protection committee of Montefiore Hospital or the Weiler hospital of the Albert Einstein Comprehensive Cancer Center whose names and phone numbers are listed at the end of this form, if at any point during the duration of this treatment you feel that you have been:

a). Inadequately informed of the risks, benefits, or alternative treatments,

Or

b). Encouraged to continue in this study beyond your wish to do so.

Voluntary Participation

Your participation is voluntary, and you may choose to refuse to participate or withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled. In addition, your participation may also be terminated without your consent if the research study doctor feels that it is in your best interest. You do not waive any rights by signing this informed consent.

GENERAL STATEMENT

This research project and its treatment procedures have been fully explained to you. All experimental procedures have been identified and no guarantee has been given about possible results. You have had the opportunity to ask questions concerning any and all aspects of the project and any procedures involved.

By signing below, you state that you are at least 18 years of age and voluntarily give your consent to participate in this research study. You will be given a copy of this consent form.

_____
Patient's Printed Name

_____ _____
Patient's signature Date

_____
Name of person conducting informed consent

_____ _____
Signature of Person conducting informed consent Date