Consent Form **S1600**

Study Title for Study Participants: Testing the Effect of Nutrition on Bladder Cancer Surgery

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: A Randomized Phase III Double Blind Clinical Trial Evaluating the Effect of Immune-Enhancing Nutrition on Radical Cystectomy Outcomes (SIMmune)

What is the usual approach to bladder cancer surgery?

You are being asked to take part in this study because you have bladder cancer and will undergo surgery to remove all of the bladder (the organ that holds urine) as well as nearby tissues and organs. In men, this includes removal of the prostate and seminal vesicles. In women, this may include the uterus, cervix, along with the fallopian tubes and ovaries. Nearby lymph nodes, and some or all of the urethra are also removed. The study group will receive the nutritional supplements of interest in the study. The control group for this study will receive a nutritional supplement but not the supplements of interest for the trial.

People who are undergoing this surgery and are not participating in a study are usually not treated with nutritional supplements.

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

If you decide not to take part in this study, you have other choices. For example:

- you may choose to have the usual approach described above, without nutritional supplements
- you may choose to take part in a different study, if one is available
- you may choose not to undergo surgery
- you may take a nutritious supplement which you purchase yourself over the counter

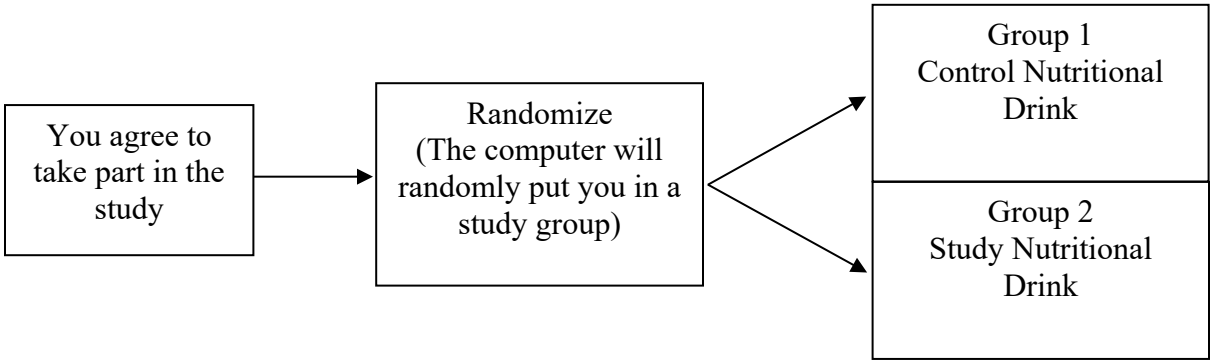
Why is this study being done?

You have bladder cancer and will be having surgery. Many patients don't get enough of certain types of nutrients before going in to surgery, which may cause infections and other problems such as muscle wasting, rapid weight loss, slow wound healing, and inflammation. The purpose of this study is to test whether improving nutrition before and after surgery can reduce the infections and other problems that sometimes occur after surgery. The effects of a special nutrition drink will be compared to a control. A control is a liquid that looks like the study liquid but does not contain the nutrients to be studied. There will be about 200 people taking part in this study.

What are the study groups?

This study has two study groups. One group will receive the study nutrition drink containing special additional nutrients, and the other group will receive the control nutrition drink that does not contain the special nutrients to be studied but is otherwise the same. We do not know if the special nutrients are helpful or harmful for your cancer. Both drinks contain milk, soy and fish ingredients. Both drinks are appropriate for these diets: lactose intolerance, gluten-free, kosher, and halal.

A computer will by chance assign you to one of the two treatment groups in the study. This is called randomization. This is done by chance because no one knows if one study group is better or worse than the other. Once you are put in one group, you cannot switch to the other group. Neither you nor your doctor can choose or will know which group you will be in. You will have an equal chance of being placed in either group.



How long will I be in this study?

You will drink the study drinks for five days before your surgery and five days after. After you finish the study drinks, your doctor will continue to watch you for side effects and follow your condition for 3 years after your surgery.

What extra tests and procedures will I have if I take part in this study?

Most of the exams, tests, and procedures you will have are part of the usual approach for your cancer. However, there are some extra exams, tests, and procedures that you will need to have if you take part in this study.

If the exams, tests, and procedures show that you can take part in the study, and you choose to take part, then you will need the following extra tests and procedures. They are not part of the usual approach for your type of cancer and will be provided at no cost to you.

During the study:

- DXA Body Scan – You will have a DXA Body Scan before surgery and another scan 30 days after surgery. The DXA Body Scan that you get in this study will expose you to low amounts of radiation. Every day, people are exposed to low levels of radiation that come from the sun and the environment around them. This type of radiation is called "background radiation. No one knows for sure whether exposure to these low amounts of radiation is harmful to your body. The DXA Body Scan that you get in this study will expose you to less radiation than you get from everyday background radiation. Most of the time, this amount of extra radiation is not harmful to you. However, scientists believe that being exposed to too much radiation can cause harmful side effects. This could include getting a new cancer. We estimate that this could happen in about 1 out of every 1000 people who get a very large amount of extra radiation. For this test you lie down on an open "table" for approximately 8 minutes while your body is scanned. The DXA test measures body fat, lean tissue and bone mineral content for the arms, legs, and trunk. Neither you nor your health care plan/insurance carrier will be billed for the DXA Body Scan that will be used for this study.

- Blood draws – You will have one blood draw before receiving the nutrition supplements prior to surgery, another blood draw 2 days after surgery, and another 30 days after surgery. At each time point, about 5 teaspoons of blood will be collected. This sample is required in order for you to take part in this study because the research on the sample is an important part of the study. Blood samples for research will be drawn at the same time as the blood draws for labs. Neither you nor your health care plan/insurance carrier will be billed for the collection of the blood sample that will be used for this study. Your privacy is very important and the researchers will make every effort to protect it. Your test results will be identified by a unique code and the list that links the code to your name will be kept separate from your sample and health information. The results will be available to the study doctor.

- Questionnaires – There will be three separate occasions you will need to complete two to three questionnaires to collect information about how you are feeling physically and emotionally, and whether you are at risk for malnutrition during your treatment. It will take about 20 minutes to complete the questionnaires. The questionnaires will be given to you before the surgery, 2 days after surgery, and 30 days after surgery. If any questions make you feel uncomfortable, you may skip those questions and not give an answer. Although the questionnaires are not part of regular cancer care, they are being conducted as part of this research study to learn more about how your diagnosis and treatment(s) are affecting your life. This information along with that collected from other patients will help researchers in better understanding patients' needs and concerns. Additionally, should you choose to stop taking the study drink early, you will still be given the questionnaires to complete.

- Calendar – You will be provided a calendar and will be asked to make note of the time that you drink the nutritional drinks. You will be asked to do this for the 5 days prior to and the 5 days after your surgery. There is also a study calendar below that shows how often the extra tests will be done as well as the schedule for the intake of the nutritional drinks.

- Phone Interview- You will be interviewed by phone to collect information about your eating habits four times. It will take about 15 minutes to complete each interview. You will be required to provide your contact information and the best times to contact you for the phone interviews in order for you to take part in the study. Two interviews will take place at the beginning of the study (before starting the nutritional drinks) and two interviews will take place about 30 days after surgery. The interview is not part of regular cancer care, but is being done as part of this research study to learn more about how your diagnosis and treatment is impacting your life. This information along with that from other patients will help researchers better address patients' needs and concerns. If you stop the study drinks early, you will still be interviewed by phone.

Here is a calendar of the study procedures:

First study visit	Blood draw for research Blood draws to test your blood count and liver function DXA body scan Complete questionnaires
Around the time of the first study visit	Phone interviews Stool sample collection before starting study drinks (optional)
Every day, for five days before surgery	Study drinks Stool sample collection after at least 4 days of taking study drinks prior to surgery (optional)
	Surgery
Every day, for five days after surgery	Study drinks Stool sample collection after return home from hospital (optional)
2 days after surgery	Blood draw for research Blood draws to test your blood count and liver function Complete questionnaire
30 days after surgery	Evaluation by surgeon for complications DXA body scan Blood draws to test your blood count and liver function Blood draw for research Complete questionnaires
About 30 days after surgery	Phone interviews
About 3, 6, 9, 12, 18, 24, and 36 months after surgery	Evaluation for complications

Optional samples: You will be given the option to store your stool samples and/or any leftover blood from the blood draws during this study in a biobank. Storing samples is called "biobanking." The biobank for the stool samples from this study is called SWOG Biobank and is supported by the NCI. The biobank for the leftover blood from this study is called the EDGE Research Lab biobank. This will be discussed in the section under "Optional studies" below.

What possible risks can I expect from taking part in this study?

- You may be asked sensitive or private questions which you normally do not discuss.
- The study approach may not be better, and could possibly be worse, than the usual approach for your cancer.

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

Possible Side Effects of both Study Nutritional Drinks:

COMMON, SOME MAY BE SERIOUS
• **Diarrhea** • **Nausea** • **Vomiting** • **Loose Stools**

What possible benefits can I expect from taking part in this study?

It is not possible to know at this time if the study approach is better than the usual approach so this study may or may not help you. This study will help researchers learn things that will help people in the future.

Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

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

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor, Institutional Review Board (IRB) or FDA

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the _____ *(insert name of center)* **Institutional Review Board at _____** *(insert telephone number)***.** *(Note to Local Investigator: Contact information for patient representatives or other individuals at a local institution who are not on the IRB or research team but take calls regarding clinical trial questions can also be listed here.)*

What are the costs of taking part in this study?

The nutritional drinks will be supplied at no charge while you take part in this study. It is possible that the nutritional drinks may not continue to be supplied while you are on the study. Although not likely, if this occurs, your study doctor will talk to you about your options.

The cost of the DXA scans and of the research blood tests will also be covered by the study.

You and/or your health plan/insurance company will need to pay for all of the other costs of treating your cancer while in this study, including the cost of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests are supplied at no charge. Before you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

You will not be paid for taking part in this study.

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

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. The study sponsors will not offer to pay for medical treatment for injury. Your insurance company may not be willing to pay for study-related injury. If you have no insurance, you would be responsible for any costs.

If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a study.

Who will see my medical information?

Your privacy is very important to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify

you. Some of your health information, and/or information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The company supporting the study, Nestle Healthcare Nutrition, and SWOG (a national cancer trials network)
- The Institutional Review Board, IRB, a group of people who review the research with the goal of protecting the people who take part in the study
- Researchers from the University of Kansas Medical Center and Louisiana State University who are involved in this study
- The Food and Drug Administration and the National Cancer Institute

Where can I get more information?

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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.

Who can answer my questions about this study?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor _____ *(insert name of study doctor[s])* at _____ *(insert telephone number).*

ADDITIONAL STUDIES SECTION:

This section is about optional studies you can choose to take part in

This part of the consent form is about optional studies that you can choose to take part in. You will not get health benefits from any of these studies. The researchers leading these optional studies hope the results will help other people with cancer in the future.

The results will not be added to your medical records and you or your study doctor will not know the results.

You will not be billed for these optional studies. You can still take part in the main study even if you say 'no' to any or all of these studies. If you sign up for but cannot complete any of the studies for any reason, you can still take part in the main study.

Circle your choice of "yes" or "no" for each of the following studies.

1. Future contact

Occasionally, researchers working with SWOG may have another research idea that relates to people who were on a SWOG study. In some cases, to carry out the new research, we would need to contact participants in a particular study. You can agree or not agree to future contact.

I agree to allow my study doctor, or someone approved by my study doctor, to contact me regarding future research involving my participation in this study.

Yes No

2. Biobanking for possible future studies

Researchers are trying to learn more about cancer, diabetes, and other health problems. Much of this research is done using samples from your blood. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure health problems.

Some of these studies may be about genes. Genes carry information about features that are found in you and in people who are related to you. Researchers are interested in the way that genes affect how your body responds to treatment.

WHAT IS INVOLVED?

If you agree to take part, here is what will happen next:

1) Any blood samples left over after the testing done for the main part of the study and some related health information may be stored in the EDGE Research Lab biobank, along with samples and information from other people who take part. The samples will be kept until they are used up. Information from your medical record will be updated from time to time.
2) A stool sample will be collected at three timepoints during the study and will be sent to the SWOG Biobank for use in future studies. The samples will be kept until they are used up. Information from your medical record will be updated from time to time.
3) Qualified researchers can submit a request to use the materials stored in the Biobanks. A science committee at the clinical trials organization, and/or the National Cancer Institute, will review each request. There will also be an ethics review to ensure that the request is necessary and proper. Researchers will not be given your name or any other information that could directly identify you.

4) Neither you nor your study doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples.
5) Some of your genetic and health information may be placed in central databases that may be public, along with information from many other people. Information that could directly identify you will not be included.

WHAT ARE THE POSSIBLE RISKS?

1) The most common risks related to drawing blood from your arm are brief pain and possibly a bruise.
2) There is a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.
3) There is a risk that someone could trace the information in a central database back to you. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.
4) In some cases, this information could be used to make it harder for you to get or keep a job or insurance. There are laws against the misuse of genetic information, but they may not give full protection. There can also be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a study. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?

Your privacy is very important to the researchers and they will make every effort to protect it. Here are just a few of the steps they will take:

1) When your sample(s) is sent to the researchers, no information identifying you (such as your name) will be sent. Samples will be identified by a unique code only.
2) The list that links the unique code to your name will be kept separate from your sample and health information. Any Biobank and SWOG staff with access to the list must sign an agreement to keep your identity confidential.
3) Researchers to whom SWOG sends your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.
4) Information that identifies you will not be given to anyone, unless required by law.
5) If research results are published, your name and other personal information will not be used.

WHAT ARE THE POSSIBLE BENEFITS?

You will not benefit from taking part. The researchers, using the samples from you and others, might make discoveries that could help people in the future.

ARE THERE ANY COSTS OR PAYMENTS?

There are no costs to you or your insurance. You will not be paid for taking part. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

WHAT IF I CHANGE MY MIND?

If you decide you no longer want your samples to be used, you can call the study doctor, _____, *(insert name of study doctor for main trial)* at _____ *(insert telephone number of study doctor for main trial)* who will let the researchers know. Then, any sample that remains in the bank will no longer be used and related health information will no longer be collected. Samples or related information that have already been given to or used by researchers will not be returned.

WHAT IF I HAVE MORE QUESTIONS?

If you have questions about the use of your samples for research, contact the study doctor, _____, *(insert name of study doctor for main trial)*, at _____ *(insert telephone number of study doctor for main trial)*.

Please circle your answer to show whether or not you would like to take part.

SAMPLES FOR FUTURE RESEARCH STUDIES:

1. **My leftover blood samples and related information may be kept in a Biobank for use in future health research.**

   YES NO

2. **My stool samples and related information may be collected and kept in a Biobank for use in future health research.**

   YES NO

This is the end of the section about optional studies.

My Signature Agreeing to Take Part in the Main Study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the main study and any additional studies where I circled 'yes'.

Participant's signature_____

Date of signature_____

Signature of person(s) conducting the informed consent discussion

_____

Date of signature_____