INSTITUTE: National Cancer Institute

STUDY NUMBER: 11-C-0129 PRINCIPAL INVESTIGATOR: Deborah E. Citrin, M.D.

STUDY TITLE: A Pilot Trial Assessing the Feasibility of Delivering Topical MTS-01 to Reduce Dermatitis in Patients Receiving Intensity Modulated Radiation with Concurrent 5-Fluoruracil and Mitomycin-C for Stage I-III Carcinoma of the Anal Canal

Continuing Review Approved by the IRB on 07/22/13
Amendment Approved by the IRB on 04/02/14 (D) Date Posted to Web: 4/11/14

Standard Consent

INTRODUCTION

We invite you to take part in a research study at the National Institutes of Health (NIH).

First, we want you to know that:

Taking part in NIH research is entirely voluntary**.**

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. However, to receive care at the NIH, you must be taking part in a study or be under evaluation for study participation.

You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Second, some people have personal, religious or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). If you have such beliefs, please discuss them with your NIH doctors or research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at NIH, or with family, friends or your personal physician or other health professional.

Why is this study being done?

The purpose of this study is to find out what effects, good or bad, MTS-01 has on your skin during chemotherapy and radiation treatment for anal cancer. Treatment with radiation and chemotherapy for anal cancer can cause irritation of the skin that can lead to redness and tenderness. In some patients the skin irritation can be severe and lead to blistering or peeling of the skin during treatment, causing discomfort and requiring breaks from radiation treatment.

MTS-01 is a drug that protects cells and tissues from the effects of radiation. The purpose of this study is to determine if treatment with MTS-01 every day before radiation treatment can reduce the irritation of the skin during chemotherapy and radiation for anal cancer.

How many people will take part in this study?

A total of 15 people will take part in this study. The dose of MTS-01 applied to the skin will be the same for every patient. All patients will receive similar doses of radiation and chemotherapy.

Description of Research Study

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

Before you begin the study, you will need to have the following exams, tests, or procedures to find out if you can be in the study. These exams, tests, or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- *History and Physical examination*
- *Biopsy of tumor*
- *CT scan of the chest, abdomen, and pelvis*
- *PET scan*
- *MRI or ultrasound of the anal tumor*
- *Basic laboratory tests including blood counts and measurement of kidney function, liver function, and electrolytes in the blood.*
- *Urine pregnancy test for females*

During the study, you will need the following tests and procedures. They are part of regular cancer care.

- *Radiation treatment planning and daily radiation treatments for six weeks*
- *Treatment with chemotherapy (mitomycin-C and 5-fluorouracil) during the radiation treatment*
- *Blood tests every week to check blood cell counts, blood electrolytes, and blood chemistries.*
- *Weekly visits with the radiation oncologist during treatment.*

You will need these tests and procedures that are either being tested in this study or being done to see how the study is affecting your body.

- *Sigmoidoscopy with biopsies (optional, see below)*
- *Treatment with the study drug, MTS-01 gel, on the skin in the groin area and between the buttocks each day prior to radiation treatment. A small area near your belly button will*

also be treated to see how your skin responds to MTS-01 without radiation (this area does not receive radiation).

- *Pictures of the skin receiving treatment with MTS-01 will be taken before treatment and at each weekly visit during treatment.*
- *You will fill out a pain questionnaire every week.*
- *If you have HIV, tests of the levels of virus in your blood will be performed every week during treatment.*

When you are finished with your radiation and chemotherapy treatment, you will continue to be seen weekly for the first month after treatment for blood tests and an examination and then every three months by the radiation oncologist. You will stop being treated with MTS-01 the same day you complete radiation and chemotherapy. You will undergo repeated physical examination, blood testing, and x-rays to see how your tumor responds to treatment.

Study Chart

Another way to find out what will happen to you during the study is to read the chart below. Start reading at the top and read down the list, following the lines and arrows.

Screening and Enrollment

- Medical History and Physical Exam
- Biopsy
- Imaging Studies to Stage Cancer
- Blood Studies, Including HIV Test
- Optional Anoscopy, Sigmoidoscopy, Cytology, and Biopsies

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Treatment

Planning

- Radiation Treatment Simulation (planning session)
- Chemotherapy planning, placement of temporary catheter in vein in arm (PICC)

Therapy

- **MTS-01 gel** will be applied to your skin in the groin areas and between the buttocks daily before each radiation treatment.
- **Radiation** Monday through Friday (5 days per week for ≈ 6 weeks).
- **Mitomycin C** by intravenous injection twice (Day 1 and Day 29)
- **5-Fluorouracil** given by intravenous infusion over four days twice,(first week and fifth week) during radiation treatment beginning the first week of radiation treatment.

Monitoring

- Review of Side Effects
- Photos of Treatment Area
- Blood Studies

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After Treatment

- Clinic Appointments for 1 year
- Blood tests
- Follow-up imaging to document response
- Follow-up sigmoidoscopy and biopsies and/or cytology(Optional)

What does this study involve?

Standard of Care Treatment:

Treatments covered under this study include 5-fluorouracil and Mitomycin-C (chemotherapies) and radiation to treat your cancer. These treatments will not be experimental. Your doctors will describe your treatment plan to you in detail before asking you to sign this consent form. You may be asked to sign a separate consent form for any treatment procedures not outlined in this consent.

Birth Control

If you are a woman who is breast feeding or pregnant, you may not take part in the study because we don't know how this medicine would affect your baby or your unborn child. If you are a woman who can become pregnant, or are the partner of a woman who can become pregnant, you will need to practice an effective form of birth control before starting study treatment, during study treatment, and for six months after you finish study treatment. If you think that you or your partner is pregnant, you should tell your study doctor or nurse at once.

Effective forms of birth control include:

- Abstinence
- intrauterine device (IUD)
- hormonal [birth control pills, injections, or implants]
- tubal ligation
- vasectomy

Alternative Approaches or Treatments

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

Instead of being in this study, you have these options**:**

- Getting treatment or care for your cancer without being in a study
- Taking part in another study

Please talk to your doctor about these and other options.

Risks or Discomforts of Participation

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects.

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

Possible side effects of MTS-01

Likely	Less Likely	Rare but Serious
• Skin irritation • Rash • Itching of the skin in the area being treated	• Low blood sugar • Nausea • Diarrhea • Low blood potassium level • Dizziness	• Blood clots

Several laboratory tests are always conducted on new drugs to determine if the drugs have the potential to alter or otherwise damage the genetic material (DNA) in the body's cells. These tests are conducted to help determine if the drug may cause cancer in humans. MTS-01 caused damage to DNA in some test-tube tests. This type of damage to DNA has been associated with the development of cancer; however, these laboratory test findings do not necessarily mean that MTS-01 could cause genetic damage in humans or increase your risk of developing cancer.

It is unknown whether MTS-01 can interfere with the effectiveness of radiation therapy in the treatment of your cancer.

Possible side effects from 5-fluorouracil and mitomycin C

Likely	Less Likely	Rare but Serious
• Mild Nausea and/or vomit • Loss of Appetite • Diarrhea • Mouth Sores • Changes in taste • Gastrointestinal discomfort • Low white blood cell count • Rash	• Infections • Anemia • Low Platelet counts • Pain • Itchy Skin • Dehydration (too much water loss from body)	• Blood clots • Severe decreases in blood cell counts (platelets, red blood cells, and white blood cells) • Changes in mental status (i.e. confusion and lack of coordination) • Chest Pain

• Nail problems • Hair loss • Headache • Fatigue		• Allergic reactions • Kidney damage • Severe skin damage at infusion site • Death

Additional Side Effects from Radiation

Some additional aide effects may occur with radiation to the pelvic area. These side effects are listed below. Your doctor will discuss these with you. It is important to let your doctor know if you develop these side effects because changes may need to be made to your treatment. The short term side effects of radiation tend to go away a few weeks after treatment is completed.

Likely	**Less Likely**
• Skin irritation in the area radiated (pelvis) • Fatigue • Diarrhea • Hair loss in the area treated with radiation	• Burning with urination or urgent urination • Decrease in blood counts • Pain in the pelvis area

Late Side Effects of Radiation

Some side effects of radiation can happen many months or years after treatment. It is impossible to predict who will develop long term side effects. Your doctor will discuss these risks with you. The possible long term side effects of radiation to the pelvis can include:

Common: increased tendency to develop gas or diarrhea, more frequent or urgent bowel movements, infertility

Uncommon: bleeding from the rectum, bleeding from the bladder, scarring of the vagina in females, decreased sexual function in males

Extremely rare: injury to the hips that could result in a fracture of bone, life-threatening tumor caused by radiation.

Potential Benefits of Participation

Are there benefits to taking part in this study?

The aim of this study is to see if MTS-01 will prevent or lessen skin irritation from chemotherapy and radiation as treatment for anal cancer. By reducing skin irritation, it is possible that MTS-01 may reduce the need for breaks from treatment due to pain or infection, which may improve the efficacy of treatment. Because there is not much information about the drug's effect on the skin, we do not know if you will benefit from taking part in this study. The information from this study may help doctors learn more about MTS-01 as a treatment for radiation skin damage. This information could help future cancer patients.

Research Subject's Rights

What are the costs of taking part in this study?

If you choose to take part in the study, the following will apply, in keeping with the NIH policy:

- You will receive study treatment at no charge to you. This may include surgery, medicines, laboratory testing, x-rays or scans done at the Clinical Center, National Institutes of Health (NIH), or arranged for you by the research team to be done outside the Clinical Center, NIH if the study related treatment is not available at the NIH.
- There are limited funds available to cover the cost of some tests and procedures performed outside the Clinical Center, NIH. You may have to pay for these costs even if they are not covered by your insurance company.
- Medicines that are not part of the study treatment will not be provided or paid for by the Clinical Center, NIH.
- Once you have completed taking part in the study, medical care will no longer be provided by the Clinical Center, NIH.

Stopping Therapy

Your doctor may decide to stop your therapy for the following reasons:
- if he/she believes that it is in your best interest
- if your disease grows during treatment
- if you have side effects from the treatment that your doctor thinks are too severe
- if new information shows that another treatment would be better for you

In this case, you will be informed of the reason therapy is being stopped.

You can stop taking part in the study at any time. However, if you decide to stop taking part in the study, we would like you to talk to the study doctor and your regular doctor first.

If you decide at any time to withdraw your consent to participate in the trial, we will not collect any additional medical information about you. However, according to FDA guidelines, information collected on you up to that point may still be provided to Mitos Pharmaceuticals or designated representatives. If you withdraw your consent and leave the trial, any samples of yours that have been obtained for the study and stored at the NCI can be destroyed upon request. However, any samples and data generated from the samples that have already been distributed to other researchers or placed in the research databases can**not** be recalled and destroyed.

Conflict of Interest

The National Institutes of Health (NIH) reviews NIH staff researchers at least yearly for conflicts of interest. The following link contains details on this process *http://ethics.od.nih.gov/procedures/COI-Protocol-Review-Guide.pdf*. You may ask your research team for a copy of the Protocol Review Guide or for more information. Members of the research team who do not work for NIH are expected to follow these guidelines but they do not need to report their personal finances to the NIH.

Members of the research team working on this study may have up to $15,000 of stock in the companies that make products used in this study. This is allowed under federal rules and is not a conflict of interest.

Optional Biopsies and/or Cytology:
You are being given the option of having 1) biopsies of tumor, and/or 2) biopsies of normal cells from the rectum and anus, and 3) collection of cell from the anus using a small brush (Cytology) before and one year after your treatment. You may consent to 0, 1 , 2, or 3 of these procedures, and participation in optional biopsies does not affect your ability your eligibility to receive treatment for your anal cancer.

For the two separate types of biopsies, your doctor will remove some small pieces of tumor and/or 15-30 small pieces of healthy tissue from the rectum and anal canal to do some research tests.

These biopsies will be performed via endoscopy. Gastrointestinal endoscopy and biopsy is a standard procedure performed in a designated endoscopy room by a qualified gastroenterologist. You will be prepared for flexible sigmoidoscopy with a gut-clearing agent (e.g., Golytely, Magnesium Citrate) and eating nothing after midnight the night before; you can still take medications. Medications to decrease anxiety and discomfort of endoscope insertion are not

routinely given to patients for flexible sigmoidoscopy, but can be given upon special request by you. A flexible tube will be inserted into the rectum that allows the operator to visualize the gut mucosa and/or to project an image of the mucosal surface onto a TV screen. At various places in the gut surface and tumor surface, small pieces of tissue will be plucked out by manipulation of tissue collecting devices at the tip of the endoscope.

The procedure itself generally lasts 15 to 30 minutes. The biopsy procedure has multiple risks. The most common side effects are minor bleeding not requiring treatment (3/100 procedures) and local pain (3/100 procedures). Rare but serious side effect include: the risk of the sedatives (if given) causing slowing or cessation of breathing (your breathing and blood oxygen level is constantly monitored, and some of the sedative effects can be reversed with other drugs); making a tear (perforation) in the lining of the bowel (1/10,000 procedures); and death (1/10,000 procedures). Any complication will be identified as soon as possible and treated appropriately which may include hospitalization, antibiotics, blood transfusion, or surgery. The endoscope is sterilized prior to use so there is minimal risk of infection from the endoscope. This procedure will be further explained to you in much greater detail during a separate informed consent.

Cytology will be performed separately. A small brush will be inserted into the anus by a doctor or nurse to collect cells.

The results of these tests will not be used to plan your care. This tissue will be used to allow us to study possible viral causes of anal cancer (Human Papilloma Virus, HPV). If you have HIV, these tests will also be used to see how the HIV virus changes with treatment.

The biopsy to be performed is exclusively for research purposes and will not benefit you. It might help other people in the future. Even if you sign "yes" to have the biopsy you can change your mind at any time. Please read each sentence below and think about your choice. After reading each sentence, circle and initial the answer that is right for you. The decision to participate in this part of the research is optional, and no matter what you decide to do, it will not affect your care.

I agree to have the anal or rectal biopsies for the research tests in this study.

Yes No Initials_____

I agree to have anal cytology for the research tests in this study.

Yes No Initials_____

Purpose of the Project

We would like to invite you to participate in a research project to discover genetic changes associated with cancer, thus potentially leading to better prevention, detection and treatment of cancer, and perhaps other diseases as well. This project is being sponsored by the National Cancer Institute (NCI), part of the government agency known as the National Institutes of Health (NIH). If you choose to participate in this aspect of the study, a piece of a biopsy from your cancer as well as a blood sample will be included in this study. **You do <u>not</u> need to participate in the HPV-Related Cancer Genomic Study in order to participate in the larger treatment study.**

Bodily tissues are made up of cells containing DNA, which is part of the unique genetic material carrying the instructions for your body's development and function. Cancer can result from changes in this genetic material, thereby causing cells to divide in an uncontrolled way and possibly to travel to other organs. Some of the genetic changes leading to cancer are currently known, however many remain to be discovered.

The HPV-Related Cancer Genome Project is designed to identify genetic changes that can cause cancer in humans. As such, we would like to study the genetic material obtained from your tumor tissue as part of this project. We will compare the genetic material from your cancerous tissue with the genetic material from your normal tissue to find any differences that may exist. By combining information about genetic differences between normal and disease tissues along with information contained in your medical records, it may be possible to identify the genetic changes that are associated with your particular type of cancer. This same process will be performed with normal and cancerous tissues obtained from a number of other people who have agreed to participate in this research project. In this way, we expect to identify most of the genetic changes associated with many different kinds of cancer. By comparing treatment responses of patients with various cancers (through recorded medical information), this project could also lead to more knowledge about why certain cancers respond differently to treatments. With such knowledge, future treatment options could potentially become customized to a patient's unique genetic make-up.

Description of the Research

Collection of Samples and Medical Information

- Your biopsy is optional. During your procedure, cancerous tissue will be removed. This will be done at the time of sigmoidoscopy (at the same time as the other biopsy if you have consented to that)

- We will collect a sample of blood (approximately 4 tablespoons), drawn from a vein in your arm, as a second type of normal tissue.
- We will also collect information from your medical records, including your age, ethnic background, diagnosis, disease history, medical treatments, and response to treatments.

Coding of Tissue Samples and Medical Information

- Your tissues and blood sample, and medical information will be labeled with a confidential project-assigned ID.
- Only Drs. Citrin and Uldrick at The Center for Cancer Research, NCI will have the information that matches the code to traditionally-used identifying information, such as your name, address, phone number, or social security number. Drs. Citrin and Uldrick will keep the information that matches the confidential code to this identifying information in a safeguarded database. Only authorized personnel, who have specifically agreed to protect your identity, will have access to this database. All materials conveyed to the HPV-Related Cancer Genome Project will be labeled with a project-assigned ID, removing traditionally-used identifying information, such as your name, address, phone number, or social security number. All other researchers and personnel, including those who will be working with your samples and medical information, will not have access to any of the traditionally-used identifying information about you.

Storage and Release of Samples and Medical Information

- Your coded tissue samples will be sent to an NCI-sponsored storage facility. The facility will process the samples and then send portions of your samples to different types of laboratories for analysis as part of this project. One type of laboratory will analyze your DNA by a method called sequencing. Other laboratories will study your samples by different methods. The remaining tissue from your samples might be stored for an unlimited period of time for use in future research related to cancer, or perhaps in other research projects if you provide consent for these studies.
- Information obtained from analyses performed on your coded samples and medical information will be entered into project databases along with information acquired from the other research participants in this project.
    - Anonymous information from the analyses, which cannot be traced to any individual patient, may be available to anyone on one of several completely public Internet databases of scientific information.
    - Information obtained from more detailed analyses, along with your confidential coded medical information, will be put into a controlled-access database. The information in this database will be available only to researchers who have received approval from an NIH Data Access Committee. In gaining access to such information, researchers have to agree to use the data only for research projects and not to ever try to use it in order to identify the donor of the material.

However, despite all of the safety measures that we will use, we cannot guarantee that your identity will never become known.

Please note that traditionally-used identifying information about you, such as your name, address, telephone number, or social security number, will NOT be put into either the public or controlled-access databases for this project.

Potential Benefits of Participating in the Project

You should not expect to personally benefit from this research, aside from the knowledge that your participation will help researchers and health professionals around the world to better understand the causes of cancer and other diseases. Research projects such as this lead to better ways to prevent, detect, treat, and cure such illnesses.

Potential Risks of Participating in the Project

Physical Risks

- There are very few physical risks associated with this project. Possible side effects from drawing the blood sample include mild pain, bleeding, bruising, and infection at the site of the needle insertion. Fainting or light-headedness can sometimes occur, but usually lasts only a few minutes. Every precaution will be taken to minimize these effects.

Psychological or Social Risks Associated with Loss of Privacy

- Your privacy is very important to us, and we use many safety measures to protect your privacy. However, despite all of the safety measures that we will use, we cannot guarantee that your identity will never become known. Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other relatives. Consequently, it may be possible that genetic information from them could be used to help identify you. Similarly, it may be possible that genetic information from you could be used to help identify them.
- While neither the public nor the controlled-access databases developed for this project will contain information that is traditionally used to identify you (your name, address, telephone number, or social security number), technology may be developed in the future that would allow someone to link your genetic or medical information in our databases back to you. For example, someone could compare information in our databases with information from you (or a relative) in another database and be able to identify you (or your relative). It is also possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information back to you. Because some genetic variations can help to predict the current or future health problems of you and your relatives, this information may be of interest to

employers, health providers, insurance companies, and others. Patterns of genetic variation also can be used by law enforcement agencies to identify a person or his/her relatives. Therefore, your genetic information could potentially be used in ways that could cause you or your family distress, such as by revealing that you (or a relative) carry a genetic disease or by leading to the denial of employment or insurance for you (or a relative).

- There also may be other privacy risks that we have not foreseen.

While we believe that the risks to you and your family are very low, we are unable to tell you exactly what all of the risks are. There are some state laws that protect against genetic discrimination by employers or insurance companies, but there is currently no federal law that prohibits such discrimination. We believe that the benefits of learning more about cancer and other diseases outweigh these potential risks.

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Cancer Institute Institutional Review Board
- The study sponsor Mitos Pharmaceuticals
- Qualified representatives from Mitos Pharmaceuticals, the pharmaceutical company who produces Tempol MTS-01.

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.

Project Results

If research from this project is published in professional journals, there will be no traditionally-used identifying information, such as your name, address, telephone number, or social security number, included in the publications. Some publications from this project will be found at the HIV Tumor Molecular Characterization Project website.

Your individual results will not be added to your medical record, and they generally will not be reported back to you. However, your doctors will periodically review results. If a gene change is identified that is not related to this research study, but has a well-established relationship to a human disease, your doctors will notify you if you choose. Such unexpected test results are known as "incidental findings".

If we find a change in a gene that is important to you or your family's health, the results will need to be confirmed in a clinical laboratory. If you want this to be done, we will draw an additional blood sample and send it for confirmatory testing. Once the results are available, if you would like to receive your results we will offer to have you come to NIH (at our expense) to have genetic education and counseling to explain this result. If you do not want to come to NIH, we will help you find a local genetic healthcare provider who can explain it to you (at your expense).

If we find gene changes that are not known to be important at this time, we will not share that information with you. As this is a rapidly changing field, it is possible that genetic variants that are not known to be important at this time may be shown to be important at a later date. If you are receiving care from another physician who thinks that this testing may be of use in your care and treatment, you may contact us at any time and we will share the results with your physician.

Please let us know your preference by initialing one of the following statements:

_[ ]___ I DO NOT want to be recontacted if genetic variants with potential health implications are discovered.

_[ ]___ I DO want to be recontacted if genetic variants with potential health implications are discovered. (You will be given a choice to learn or not learn about a genetic change that we find.)

Financial Compensation/Costs

You will not be paid to participate in this project. Your tissue samples and your medical information will be used for research purposes only and will not be sold. It is possible that some of the research conducted using your tissue samples or medical information will eventually lead to the development of new diagnostic tests, drugs or other commercial products. Should this occur, you will not receive any part of the profits generated from such products.

Alternatives to Participating in the Project
The alternative option is not to participate in this project.

Voluntary Participation
The choice to participate in this research by donating your tissues and medical information is completely up to you. **No matter what you decide, your decision will not affect your medical care**.

Withdrawal from the Project
Once your coded samples have been distributed to the participating research laboratories and centers, and your information transferred to the appropriate databases, you will **not** be able to withdraw your information from this research project. However, you may be able to request the return or destruction of the tissue samples if you so desire.

My tissue and blood may be used in the Anal Cancer Genome Project

Yes No Initials_____

Additional Optional Studies
We would like to keep some of the tissue and blood that are collected for future research. These specimens will be identified by a number and not your name. The use of your specimens will be for research purposes only and will not benefit you. It is also possible that the stored specimens may never be used. Results of research done on your specimens will not be available to you or your doctor. It might help people who have cancer and other diseases in the future.

If you decide now that your tissue and blood can be kept for research, you can change your mind at any time. Just contact us and let us know that you do not want us to use your tissue, blood, and urine. Then any tissue and blood that remain will be destroyed.

Please read each sentence below and think about your choice. After reading each sentence, circle and initial the answer that is right for you. No matter what you decide to do, it will not affect your care.

1. My tissue, blood, and urine specimens may be kept for use in research to learn about, prevent, or treat cancer.

Yes No Initials_____

2. My specimens may be kept for use in research to learn about, prevent or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease).

Yes No Initials_____

3. Someone may contact me in the future to ask permission to use my specimen(s) in new research not included in this consent.

Yes No Initials_____

HIV Testing

As part of this study, we will test you for infection with the human immunodeficiency virus (HIV), the virus that causes AIDS. If you are infected with HIV you will be able to participate in this study. We will tell you what the results mean, how to find care, how to avoid infecting others, how we report newly diagnosed HIV infection, and the importance of informing your partners at possible risk because of your HIV infection.

OTHER PERTINENT INFORMATION

1. Confidentiality. When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or authorized hospital accreditation organizations.

2. Policy Regarding Research-Related Injuries. The Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

3. Payments. The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines.

4. Problems or Questions. If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Deborah Citrin, M.D., CRC, B2-3500, Telephone: 301-496-5457. You may also call the Clinical Center Patient Representative at (301) 496-2626. If you have any questions about the use of your tissue for future research studies, you may also contact the Office of the Clinical Director, Telephone: 301-496-4251.

5. Consent Document. Please keep a copy of this document in case you want to read it again.

COMPLETE APPROPRIATE ITEM(S) BELOW:	
A. Adult Patient's Consent I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study. _____ _____ Signature of Adult Patient/Legal Representative Date _____ Print Name	**B. Parent's Permission for Minor Patient.** I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study. (Attach NIH 2514-2, Minor's Assent, if applicable.) _____ Signature of Parent(s)/Guardian _____ Print Name
C. Child's Verbal Assent (If Applicable) The information in the above consent was described to my child and my child agrees to participate in the study. _____ _____ _____ Signature of Parent(s)/Guardian Date Print Name	
THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM JULY 22, 2013 THROUGH JULY 21, 2014. _____ _____ _____ Signature of Investigator Date Signature of Witness _____ _____ Print Name Print Name	