IRB APPROVED
AS MODIFIED
Aug 18, 2025

Informed Consent/Authorization for Participation in Research

TITLE: Randomized Pre-surgical Window-of-Opportunity Trial of TTI-101 in Patients with Stage I-IV Resectable HPV-negative Squamous Cell Carcinoma of the Head and Neck

PROTOCOL NO.: 2022-0001
WCG IRB Protocol #20231280

SPONSOR(S): MD Anderson Cancer Center

INVESTIGATOR: Andrew Sikora, MD, PhD
1515 Holcombe Blvd
Houston, Texas 77030
United States

STUDY-RELATED PHONE NUMBER(S): 713-745-4851
713-792-2121 (24-hours)

_____ _____
Participant's Name Medical Record Number

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

Key Information

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are invited to take part in a research study because you have a type of cancer called HPV-negative squamous cell carcinoma of the head and neck that is planned to be removed by surgery.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The goal of this clinical research study is to learn if TTI-101 can reduce the growth of HPV-negative squamous cell carcinomas of the head and neck when given before standard of care surgery.

This is an investigational study. TTI-101 is not FDA-approved or commercially available. It is currently being used for research purposes only. The study doctor can explain how the study drug is designed to work.

How long will the research last and what will I need to do?

You are expected to be in this research study for up to 3½ weeks, followed by up to 2 years of follow-up.

You will be asked to attend clinic visits, have routine tests done, have blood samples and biopsies taken, receive the study drug, and attend follow-up visits.

More detailed information about the study procedures can be found under ***"What happens if I agree to be in this research?"***

Is there any way being in this study could be bad for me?

The study drug is still in early stages of development, and not many effects of the drug are known. Some possible risks of participating in this study include diarrhea, abdominal pain, abnormal liver enzymes, change in appetite, fatigue, nausea, vomiting, and other unknown side effects.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

The study drug may help to control the disease. Future patients may benefit from what is learned. However, it cannot be promised that there will be any benefits to you or others from your taking part in this research.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate, not participate, or discontinue participation at any time without penalty or loss of your regular benefits.

Instead of being in this research study, your choices may include: receive standard therapy, receive another investigational agent if available, or not receive treatment for cancer at all. In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of your cancer. These alternative treatments have risks and benefits that may be the same or different than those in this research study. The study doctor can discuss these alternative treatments, including their risks and benefits with you.

If you decide that you don't want any more active treatment, one of your options is called "comfort care." Comfort care includes pain medication and other support. It aims to maintain your comfort and dignity rather than cure disease. Usually this care can be provided at home.

If you think you might prefer comfort care, please discuss this with your family, friends, and your doctor.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

Who can I talk to if I have questions or concerns?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the study chair at 713-745-4851.

This research has been reviewed and approved by an Institutional Review Board (IRB – an ethics committee that reviews research studies). You may talk to them at (713) 792-6477 or IRB_Help@mdanderson.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or clientcare@wcgclinical.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

How many people will be in this study?

It is expected about 33 people at MD Anderson will be enrolled in this research study.

What happens if I agree to be in this research?

Screening Tests

Signing this consent form does not mean that you will be able to take part in this study. The following screening tests will be done within 14 days (+/- 3 days) before your first dose of study drug to help the doctor decide if you are eligible:

- You will have a physical exam and vital signs.
- You will have an electrocardiogram (EKG) to check your heart function.
- Blood (about 10 teaspoons) and urine will be collected for routine tests and for biomarker testing.
  - Biomarkers are found in the blood and may be related to your reaction to the study drug.
  - If you can become pregnant, the urine and/or blood sample will include a pregnancy test. To take part in this study, you must not be pregnant.
- You will have a tumor biopsy to test for tumor markers. This biopsy may be part of your standard of care, or it may be a separate procedure done as part of this

study. Tumor markers may predict response to TTI-101. The type of biopsy you have will depend on the location of the tumor. The study doctor will tell you more about the procedure and risks to this biopsy.
- You will have tumor assessment by clinical examination or photographic measurements.
- If the study doctor thinks it is needed, you will have either an MRI, an MRE scan, or a CT scan to check the status of your disease.

The study doctor will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in the study, you will not be enrolled. Other treatment options will be discussed with you.

Study Groups

If you are found to be eligible to take part in this study, you will be randomly assigned (like a coin toss) to either receive the study drug or be in a control group (regular standard of care treatment only). There will be a twice likely chance of you being assigned to receive the study drug. The study drug will be administered at the same dosage for all participants assigned to the study drug group.

Study Drug Administration

You will take TTI-101 2 times a day (1 dose in the morning, 1 dose in the evening) while you are on the study. Each dose should be taken with at least a cup (8 ounces) of water.

All doses should be taken at least 1 hour before a meal or 2 hours after a meal. Swallow the capsules whole and do not bite into them, break or open them, or try to dissolve them in water.

On the evening of surgery, you will need to take your final dose of study drug.

Study Visits

Week 1:
- You will have a physical exam and vital signs checked, a review of other medications you are taking, and a review of any side effects.
- You will have a tumor assessment by clinical examination or photographic measurements.

Week 2:
- You will have a physical exam and vital signs checked, a review of other medications you are taking, and a review of any side effects.

- Blood (about 7 teaspoons) will be drawn for routine and biomarker testing.
- You will have a tumor assessment by clinical examination or photographic measurements.
- You will have an electrocardiogram (EKG) to check your heart function, and again at any time if your doctor thinks it is necessary.

Week 3 (the visit before surgery):

- You will have a physical exam and vital signs checked, a review of other medications you are taking, and a review of any side effects.
- Blood (about 7 teaspoons) will be taken for both routine and biomarker testing.
- You will have a CT or MRI scan of your neck.
- You will have a tumor assessment by clinical examination or photographic measurements.

Week 4 (the day of surgery):

- You will have a check of your vital signs.
- Blood (about 2 teaspoons each) will be drawn for biomarker and pharmacodynamic (PD) testing.
- Blood (up to 2 teaspoons) will be drawn for pharmacokinetic (PK) testing at the start of the surgery. PK testing measures the amount of study drug in the body.
- After the tumor has been removed during surgery, researchers will collect a part of the removed tumor tissue for biomarker and PD testing.

End-of-Study Visit

About 30 days after you stop taking the study drug:

- You will have a physical exam and vital signs checked, plus a review of any side effects.
- Blood (about 2 teaspoons) will be drawn for biomarker testing.

Follow-Up

- After you stop taking the study drug, your health data will continue to be collected until you can no longer be contacted, you withdraw your consent, or the study is ended, whichever comes first.
- Long-term follow-up will continue by phone call or reviewing your medical record every 3-4 months for up to 2 years after treatment.
- A review of any side effects will be done at least 30 days after your last dose of the study drug.
- Blood (about 2 teaspoons each) will be collected 3-6 weeks after you have completed radiation therapy.
- Blood (about 2 teaspoons each) will be collected at follow-up visits 3, 6, and 12 months after you have stopped taking the study drug.
- Blood (about 2 teaspoons) will be collected if the tumor grows back.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for the following:

- Tell the study doctor/study staff about all medications that you are taking or plan to take, including prescription and over-the-counter medications, supplements, vitamins, and herbal remedies.
- You must not take any other investigational drugs while on this study and for 28 days after the last dose of the study drug.
- You should not schedule any surgeries while taking part in this study. If you have an unplanned surgery, tell your study doctor right away, as you may not be able to continue taking the study drug

What happens if I say yes, but I change my mind later?

You can leave the research at any time; it will not be held against you.

You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor who can then decide if you need to have any visits or tests to check on your health. It may be dangerous to suddenly stop the study treatment. If you withdraw from this study, you can still choose to be treated at MD Anderson.

If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Is there any way being in this study could be bad for me? (Detailed Risks)

While on this study, you are at risk for side effects. You should discuss these with the study doctor. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. You may also want to ask about uncommon side effects that have been observed in small numbers of patients but are not listed in this form. Many side effects go away shortly after treatment is stopped, but in some cases side effects may be serious, long-lasting or permanent, and may even result in hospitalization and/or death.

Side effects will vary from person to person, and some may occur after you have stopped receiving treatment. Tell the study staff about any side effects you may have, even if you do not think they are related to the study drugs/procedures.

You are also at risk for side effects due to the study drug that could delay starting other treatments, including your planned surgery that could help control the disease.

TTI-101 Side Effects

We do not know all the possible side effects of the study drug, TTI-101. Like all drugs, the study drug can cause side effects, although not everybody gets them. Most side effects are mild to moderate. However, some people may experience serious side effects and may require treatment.

Out of the 243 people who have received TTI-101 across multiple studies, the following occurrences of side effects have been reported.

Very common (in at least 20%):	• Diarrhea
Common (in less than 20% but greater than 5%):	• Abdominal pain • Abnormal liver enzymes • Change in appetite • Fatigue • Nausea • Vomiting
Uncommon (in 3 - 5%):	• Headache • Increased white blood cells • Shortness of breath • Swelling of the body
Rare (in less than 3%):	• Abnormal taste sensation • Acute kidney injury • Allergic reaction • Belching • Blood becoming more acidic • Blood clot to the lung • Change in color of urine • Changes in heart rhythm • Chest pain or discomfort • Chills • Common cold • Confusion

	• Constipation • Cough • Decrease in sensation • Decreased lung function • Decreased platelets • Decreased white blood cells that may lead to increased risk of infection • Dehydration • Difficulty falling or staying asleep • Distortion of sense of smell • Dizziness • Dry mouth • Dry skin • Excess protein in the urine • Fainting • Fast breathing • Feces discoloration • Fever • Gastrointestinal bacterial infection • Generalized weakness • Heartburn • High blood sugar • High cholesterol • High potassium • High uric acid in the blood • Inability to eat a full meal • Increased bilirubin in the blood • Increased phosphorus in the blood • Increased shedding of tears • Inflammation of the colon • Inflammation of the lung • Inflammation of the mouth and lips • Inflammation of the pancreas • Itchy skin • Light sensitivity • Loss of hair • Low albumin • Low blood pressure • Low blood pressure from posture change

	• Low magnesium • Low phosphate in the blood • Low potassium • Low red blood cell count • Low sodium in the blood • Low thyroid hormone levels • Nights sweats • Open sore in the skin • Pain • Pain at ostomy site • Pain or burning sensation when urinating • Painful muscles • Pneumonia • Rapid heart beat • Rash • Severe blood infection • Severe low blood pressure • Short attention span • Weakened heart • Weight gain • Weight loss • Yeast infection of the mouth

Other Side Effects

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

Having **biopsies** performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the biopsies. An allergic reaction to the anesthetic may occur. A scar may form at the biopsy site.

EKGs and ECHOs may cause discomfort while lying on the exam table, and the tape on the EKG pads may cause skin irritation.

During the **MRI**, you may feel mild vibrations throughout your body. The machine will produce a loud knocking noise. This is normal. You will be given earplugs to protect your ears. Some people, especially those who tend to feel uncomfortable in small or

closed spaces, may feel “closed in” and become anxious while in the scanner. The scanner has an intercom, which will allow you to speak to the staff during the procedure. If you feel ill or anxious during scanning, tell the MRI staff and the scanning will be stopped if you wish. The MRI will require a catheter to be inserted into one of your veins in order to inject the MRI contrast agent. This may cause skin irritation, bleeding, and/or infection. You may have an allergic reaction to the contrast agent.

The magnetic field used in MRI scanning may harm you if you have certain types of metal in your body (as might be found in pacemakers, neurostimulators, or certain clips). It may cause problems with devices, such as pacemakers. If you have metal in your body or devices such as a pacemaker, you should discuss this with the study doctor.

CT scans send x-rays through the body at many different angles. You will be exposed to a small dose of radiation. All radiation adds up over a lifetime and may increase the risk of new cancer forming. Some people may feel “closed in” while lying in the scanner. However, the scanner is open at both ends, and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or radiology technicians will give comfort, or the scanning will be stopped. Solution may also be given by vein to make the x-ray pictures more accurate. This may cause an uncomfortable feeling of warmth, nausea, and/or severe allergic reactions. The solution injection may also cause pain, bleeding, bruising, hives, and/or itching.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

You will be told about any new information that may affect your health, welfare, or choice to stay in the research.

Pregnancy Related Risks

Taking part in this study can result in risks to an unborn or breastfeeding baby, so you should not become pregnant, breastfeed a baby, or father a child while on this study.

Birth Control Requirements: If you can become pregnant or father a child and you are sexually active, you must use birth control starting during the treatment period and for at least 3 months (males and females) after your last dose of study drug.

Acceptable forms of birth control include 2 barrier methods (such as a condom or cervical cap used together), or 1 barrier method plus one of the following birth control methods:

- Spermicide
- Intrauterine device (IUD)
- Hormonal Injection
- Implant under the skin
- Hormonal birth control pills

Females: If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, you must tell your doctor right away.

Getting pregnant will result in your removal from this study.

Males: Tell the doctor right away if your partner becomes pregnant or suspects pregnancy. If your partner becomes pregnant while you are on this study, the sponsor would like to collect information about the pregnancy. The study sponsor's contact information will be made available so that, if you and your partner wish to, you can share information about the outcome of the pregnancy with the sponsor. If you and/or your partner choose not to share this information, it will not result in any penalty or loss of benefits to which you are otherwise entitled.

Will it cost anything to be in this study? Will I be paid to be in this study?

TTI-101 will be provided at no cost to you during the study.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

You will not receive any compensation for taking part in this study.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who need to review this information. Complete secrecy cannot be promised. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

A participant study number will be assigned to you once you have been enrolled in the study. This participant study number will be used to identify your data in the study report and when reporting any data from the study.

Any personal information that could identify you will be removed or changed before data are shared with other researchers or results are made public.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

The sponsor, monitors, auditors, the IRB, and the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. The results of this research may be published. However, your name and other identifying information will be kept confidential.

Federal law provides additional protections of your medical records and related health information. These are described below.

Will my data or samples be used for future research?

Your personal information and/or samples are being collected as part of this study. These data and/or samples may be used by researchers at MD Anderson, Tvardi Therapeutics, Inc., and the National Institutes of Health (NIH), or shared with other researchers and/or institutions for use in future research.

In some cases, all of your identifying information may not be removed before your data or research samples are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the MD Anderson IRB before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or shared with another researcher for future research studies without your additional informed consent.

Can I be removed from the research study without my permission?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include if the disease gets worse, if intolerable side effects occur, or if you are unable to follow study directions.

What happens if I get hurt from being in this study?

If you get sick or hurt and it is related to your participation in this study, you will be given care at MD Anderson (if you are at the clinic when you are sick or hurt). If you get hurt or sick and you are not at the clinic (for example, you are at home or at another doctor's office):

- call your personal doctor right away (or in an emergency, call 911)
- tell your personal doctor or ER staff that you are in this study (try to give them a copy of this consent form or show them your participant card)
- If you suffer a study-related injury, you may contact the Chair of the study, Dr. Andrew Sikora, at 713-745-4851, or 713-792-2121 (24-hours) with any questions you may have. By signing this consent form, you are not giving up any of your legal rights

You will not routinely be reimbursed for expenses or compensated financially by MD Anderson for this injury. Costs of treatment received because you were hurt or sick will be billed to you or your insurance company. No other form of payment is routinely available.

What else do I need to know?

This research is being funded by Tvardi Therapeutics, Inc. and the NIH.

Conflict of Interest

David Tweardy (Collaborator and Institutional Decision Maker) serves on the Board of Directors, owns stock in, and has received compensation as a Scientific Advisor from Tvardi.

David Tweardy (Collaborator) has received compensation for providing services to Tvardi Therapeutics. The financial interests are within the limits of the conflict of interest policy.

There is a significant financial relationship between MD Anderson and Tvardi Therapeutics, Inc. There is also a financial relationship between an Institutional Decision Maker (David Tweardy (Collaborator and Institutional Decision Maker)) and Tvardi Therapeutics, Inc. Both relationships have been identified as a financial conflict of interest.

The results of this study may result in a financial benefit for MD Anderson and David Tweardy.

MD Anderson has taken steps to manage this financial conflict of interest. The plan to manage the conflict has been approved by the Executive Vice Chancellor for Health Affairs for The University of Texas System.

This financial conflict of interest may affect your willingness to take part in this study. If you have any questions or concerns related to MD Anderson's significant financial relationship or David Tweardy's financial relationship with Tvardi Therapeutics, Inc. please call the MD Anderson Institutional Compliance Office at 713-745-6636. That office will provide you the contact information for a non-MD Anderson ethicist who can assist with your questions and concerns. In the event, a non-MD Anderson ethicist is not available, an MD Anderson ethicist will contact you to assist with your questions and concerns.

MD Anderson may benefit from your participation and/or what is learned in this study.

Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Most tests done on samples in research studies are only for research and have no clear meaning for health care. In an unlikely event that the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will contact you to let you know what they have found. If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

This research study involves genetic testing. The Genetic Information Nondiscrimination Act (GINA) prohibits health insurers or health plan administrators from requesting or requiring genetic information of you or your family members, or using such information for decisions regarding your eligibility for insurance or your premiums. However, this law does not provide the same protection for disability, life insurance, or long-term care insurance. GINA also prohibits most employers (with 15 employees or more) from using genetic information when making decisions on your employment, including decisions related to hiring, firing, promotion, pay, and job assignments. Please contact the study doctor if you would like more information about GINA and how it protects you from genetic discrimination.

It is not anticipated that whole genome sequencing will be done on your samples.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
   - The IRB and officials of MD Anderson
   - Tvardi Therapeutics, Inc., who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study, and/or licensees of the study technology
   - The NIH
   - The Executive Vice Chancellor (EVC) and the Office of General Counsel for the University of Texas System
   - Any future licensees of the study technology and an External Data Safety and Monitoring Board (DSMB)
   - Western Copernicus Group Institutional Review Board (WCG IRB)
   - A non-MD Anderson ethicist
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

   The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants and may be re-disclosed.

   Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. 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.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT