Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

Phase II Trial of Nivolumab, an Anti-PD-1 Monoclonal Antibody, as a Novel Neoadjuvant Pre-Surgical Therapy for Locally Advanced Oral Cavity Cancer

CTO# 102510
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A. PURPOSE OF THE RESEARCH

You are being asked to volunteer to participate in a research study. This form contains information about the study, which your doctor will explain so you can decide if you want to participate. This study is for subjects with locally advanced oral cavity cancer.

Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

The purpose of this study is to look at the effectiveness of nivolumab in patients with oral cavity cancer that can be removed by having surgery. The researchers want to see if giving nivolumab before surgery improves the results of that surgery. You are being asked to participate in this study because you have oral cavity cancer that can be removed by having surgery.

Nivolumab is not approved by the United States Food and Drug Administration (FDA) for your type of cancer. Nivolumab has been approved for different types of cancer. It is experimental, but the FDA has given its permission for nivolumab to be tested in this research study.

The study is sponsored by the Medical University of South Carolina (MUSC). The investigator in charge of this study is Dr. David Neskey. Bristol Myers Squibb (BMS) is supplying the drug nivolumab. BMS is also providing payments to MUSC and Dr. Neskey to support activities that are required to conduct and manage the study. No one on the research team will receive a direct payment or an increase in salary for conducting the study.

Up to 19 subjects will be enrolled to this study at MUSC.

B. PROCEDURES

If you agree to be in this study, the following will happen:

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. Some of these exams, tests or procedures are part of regular 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 the study doctor.

- History and physical exam. Your doctor will also review any medications you are taking.
- Vital signs (heart rate, breathing rate, and blood pressure), weight, height
- Blood tests to look at blood cell counts (numbers of each type of blood cells), chemistries (elements and minerals in your blood), and thyroid function. You will also have a hepatitis B and C screening. The amount of blood taken at this blood draw is about 20ml or 4 teaspoons.
- Serum pregnancy test for women who may be able to have children (about 5 mL or 1 teaspoon of blood)
- If you are a woman of childbearing potential or a man capable of fathering a child before, during, and/or after participation, you must use an acceptable form of birth control. Examples include: birth control pills, patch, IUD, condom, sponge, diaphragm with spermicide, or avoiding sexual activity that could cause you or your partner to become pregnant.
- Radiographic scans using Computed Tomography (CT) scan (a series of images taken with x-rays), magnetic resonance imaging (MRI) or positron emission tomography (PET) scan of the chest, pelvis and abdomen. These scans will give a detailed picture of the areas of the body taken from different angles. The procedure for this is described below.

  A CT scan is a way to make x-ray images of the inside of the body. The CT scanner is a doughnut-shaped machine that uses x-rays to create computer pictures that show structures inside your body more clearly than regular x-ray pictures. During the procedure, a technologist will take you into the CT scan room where you will lie down on the patient table (usually on your back) inside of the CT machine. You should get comfortable because it is very important not to move during certain parts of the test.

  CT examinations differ depending on the part of your body being studied. For example, if your abdomen is being studied, a series of pictures will be taken from your lower chest to your lower pelvis. During the study, you will be asked to hold your breath so that the pictures will not be blurred. The machine will make some noise, and the table will move during the scan. Also, you may receive signals from the technologist or from the machine about your breathing. Before or during the study, you may be given an injection of a contrast liquid in your vein to allow the radiologist to obtain clearer images of your organs. If you have any discomfort during the test or after the injection, be sure to tell the technologist. If your study doctor finds that you do not meet the specific eligibility requirements to be in this study, you will not be able to participate. You will continue to see your regular doctor who will discuss with you additional options for your disease.

  MRI uses a magnet and radio waves to make diagnostic medical images of the body. You will be placed on a narrow bed and then slid into a small tunnel approximately 6 feet in length and 25 inches in diameter. You will hear a loud machine-like noise.

  A PET Scan is a diagnostic tool used to detect cancer and find out the cancer's stage (a way of describing where the cancer is located, if or where it has spread, and whether it is affecting the functions of other organs in the body).

If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will be registered to the study and will begin study participation.

During the Study:

Nivolumab will be given every two weeks at a dose of 3mg/kg. Nivolumab will be given by a needle in the vein (called intravenously, or IV) over about 60 minutes. You will either have three or four doses, depending on how your disease responds to the drug.

Day 1:

- Your tumor will be photographed to look at the tumor size and to document other characteristics. Your tumor will also be measured using a tool called a caliper.
- Physical exam. Your doctor will also review any medications you are taking.
- Vital signs and weight
- Blood tests to look at blood cell counts and chemistries. The amount of blood taken at this blood draw is about 3 teaspoons or 15 mLs.
- Research procedures:
    - About 6 teaspoons or 30 mLs of blood will be drawn to look at how your body is reacting to the study drug
    - A biopsy of the tumor will be performed if it has not been previously completed. With this type of biopsy, the abnormal cells of the tumor are removed and looked at it under a microscope.

Day 15:

- Physical exam. Your doctor will also review any side effects you may be feeling.
- Vital signs and weight
- Blood tests to look at blood cell counts and chemistries. The amount of blood taken at this blood draw is about 3 teaspoons or 15 mls.

Day 29:

- Physical exam. Your doctor will also review any side effects you may be feeling.
- Vital signs and weight
- Blood tests to look at blood cell counts and chemistries. The amount of blood taken at this blood draw is about 3 teaspoons or 15 mLs.
- Serum pregnancy test for women who may be able to have children (about 1 teaspoon or 5 mls of blood)
- You will have scans to see how your disease is responding to the study drug.
- Your tumor will be photographed to look at the tumor size and to document other characteristics. Your tumor will also be measured using a tool called a caliper.

If your disease has gotten worse, you will have surgery on or around day 36.

If your disease is the same or better, you will have one more dose of nivolumab on or around day 43 and then proceed to surgery. ***On day 43,*** you will have the following tests or

assessments:

- Physical exam. Your doctor will also review any side effects you may be feeling.
- Vital signs and weight
- Blood tests to look at blood cell counts and chemistries. The amount of blood taken at this blood draw is about 3 teaspoons or 15 mLs.

Surgery:
The surgery will be completed as an inpatient procedure and you will need to stay in the hospital overnight for recovery. Your doctor will explain the procedures and risks of the surgery.

During surgery, you will have the following research procedures:

- A portion of the tumor that is removed will be done for tissue collection. With this type of biopsy, the abnormal cells of the tumor are removed and looked at it under a microscope.
- Research blood collection. About 30 mL or 6 teaspoons will be drawn to look at how your body is reacting to the study drug.

After the study:
After you the end of study visit, you will enter a follow up period. The study team will follow your care by clinic visit, review of medical record and/or telephone call every 3 months for up to 2 years.

For women of childbearing potential, you will have a serum pregnancy test 30 days and 70 days after your last nivolumab dose.

Optional Genomic Research Study
If you choose to participate in this optional genomic research study, an extra 5mLs of blood (1 teaspoon) will be drawn on day 1and then again on the day of surgery to look at your genome or your genetic code. To do this, researchers will look at your DNA to look to see if there are any variations in your DNA that may cause disease. The results of this genomic testing will not be shared with you. The results will not be used to make any decisions regarding your health. This genomic research study is optional. You do not have to agree to participate in this additional blood draw. If you choose not to participate, you can still participate in the main research study.

Please read each sentence below and think about your choice. After reading each sentence, circle "Yes" or "No" and initial next to your choice. No matter what you decide, it will not affect your care.

Optional Genomic Research Study
I voluntarily and freely give permission for an additional blood draw on day 1 and the day of surgery. The blood collected will be solely used for the research study.

YES _____ NO_____

Withdrawal

Taking part in this study is voluntary. You do not have to be in this research study. You can agree to be in the study now and change your mind later. You may discontinue your study participation at any time. Your decision will not affect your regular care. It will not affect your getting all the care, medicine, and equipment you should be getting.

The study doctor, BMS or the FDA can take you out of the study at any time with or without your agreement. These decisions will be made if:

- It is in your best medical interests to stop your participation
- You do not follow instructions
- The study is canceled.

The doctor will explain the reasons for doing so and will help arrange for your continued care by your own doctor, if needed. If you leave the study for any reason, you will be asked to have the procedures completed for the final visit.

If you cancel your permission after you have started in the study, the study staff and the study doctor will stop collecting your health information. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study or receive any drug as part of the study. This is because the study staff and/or the Study doctor would not be able to collect the information needed to evaluate the study drug.

C. DURATION

It is estimated that the study visits will take 1-3 hours, depending on the clinic schedules. Your surgery will require an overnight stay.

You will have either three or four doses of study drug. You will have surgery within one week of completing nivolumab. The total time on study is expected to be about 5-7 weeks. You will be followed every 3 months for up to 24 months.

D. RISKS AND DISCOMFORTS

Nivolumab

Nivolumab may cause one or more of the side effects listed below. This information is based on data from cancer subjects in other clinical trials with nivolumab. In addition, there may be side effects that are not yet known that may occur. You should tell your doctor or nurse right away about any possible side effects you experience.

Most common side effects (in greater than 10% of patients)

- swelling, including swelling in the hands and feet
- Extreme tiredness or fatigue

- Headache
- Tingling and/or numbness in the hands and feet
- Changes to the skin including: rash, itching skin, loss of skin color, scaling of the skin
- Changes to your blood chemistries, including low sodium, low or high calcium, low or high potassium, low magnesium
- Changes to your blood counts, including increased triglycerides and cholesterol. Some of your white blood cell counts may also be lowered, which could lead to risk of infection.
- Decreased thyroid function levels
- Diarrhea
- Low blood sugar
- Inflammation in the lining of the colon
- Decreased appetite
- Nausea and vomiting
- Constipation
- Changes to pancreatic function
- Abdominal pain
- Low hemoglobin count, which could cause fatigue
- Low platelet count, which could increase risk for bruising
- Increase in liver function tests
- Development of antibodies, which may cause your body to reject nivolumab
- Weakness, muscle pain, back pain, joint pain
- Upper respiratory tract infection
- Cough, shortness of breath
- Fever
- Infusion related reaction

Less common side effects (in between 1% and 10% of patients)

- abnormal heartbeat
- Blood clots in the lungs
- Dizziness
- A condition called peroneal nerve palsy (drop foot) which can affect your ability to lift the foot at the ankle
- Motor dysfunction
- Changes to the skin including: a red, patchy skin rash; a scaly, itchy rash; hives;
- Increased thyroid function
- A condition called adrenal insufficiency, in which the adrenal glands do not produce enough steroid hormones. If left untreated, this can cause abdominal pain, vomiting, muscle weakness, fatigue, depression, low blood pressure, weight loss, kidney failure and changes in mood.
- Diabetes
- Hypersensitivity reaction, which may have similar symptoms to an allergic reaction
- A chronic disease of the joints called spondyloarthropathy, which may have similar

symptoms to arthritis
- Inflammation in the eye
- Renal disease which can lead to renal failure
- Inflammation in the kidney
- Renal insufficiency, which is caused by the kidneys losing the ability to remove waste from the body
- Pleural effusion, which is a build-up of fluid between the tissues that line the lungs and the chest
- Respiratory failure
- Lung Inflammation (pneumonitis): It is possible that nivolumab may cause inflammation of the tissues of the lung. This adverse effect has been reported infrequently in patients treated with nivolumab. While many patients with x-ray or CT abnormalities have not developed any symptoms, some patients have developed mild to severe symptoms and in rare cases, death has occurred as a result of their lung inflammation. Signs and symptoms of lung inflammation may include difficulty breathing, pain or discomfort while breathing, chest pain, cough, shortness of breath, increased rate of breathing, fever, low blood oxygen levels, or fatigue.

  Your study doctor and nurse will watch you closely for changes in your ability to breathe and for other signs or symptoms that might show you are developing this type of lung inflammation and will perform regular tests including physical exams, measurement of oxygen levels through non-invasive testing (i.e., pulse oximeter), blood tests, chest x-rays and/or CT scans.

  Please inform your study doctor or nurse AT ONCE if you experience any of the following:
  - Any new or increased shortness of breath;
  - Any new or increased chest pain;
  - Any new or increased pain/difficulty while breathing;
  - Any new or increased cough or any significant change in your type of cough; for example any new or increased mucous or blood in your cough;
  - Any change in the amount of oxygen you require;
  - Any fever, fatigue, or other symptoms that occur at the same time as any changes to your breathing or other lung symptoms.

  If you start to develop symptoms, your study doctor will ask you to return to the clinic for additional tests, which could include a physical exam, measurement of oxygen levels, blood tests, chest x-rays, and/or CT scans. You will be monitored very closely for changes in your overall lung symptoms, monitoring may require hospitalization. You may require specific treatment in order to control pneumonitis. You may also be seen by a special doctor called a pulmonologist, who has special training to be an expert in how your lungs work.

  Prolonged treatment with medicines that suppress inflammation, sometimes needed to

manage the side effects of nivolumab treatment, may lower your body's ability to fight off certain infections (i.e., opportunistic infections). These infections may require treatment with antibiotic or antifungal medications and may be fatal.

Rare side effects (less than 1% of patients)

- Inflammation in the upper part of the intestine and/or the stomach
- Inflammation of the brain
- Facial paralysis
- Autoimmune disorders, including Guillain-Barre syndrome (associated with progressive muscle weakness or paralysis)
- Liver failure
- Pituitary gland inflammation
- Inflammation of the pancreas
- Pituitary insufficiency, which is caused by the pituitary gland not secreting enough pituitary hormones.
- Pneumonia
- Inflammation of the muscles and joints around the shoulders and hips
- A condition called sarcoidosis, which is when tiny collections of inflammatory cells grow in different parts of the body.
- An infection called sepsis
- A disorder called sixth nerve palsy which causes the eye to turn out

Risk of Delaying Surgery

If you experience certain side effects, your surgery (which could potentially cure your disease) could be delayed or cancelled completely. Please talk to your study doctor about any concerns you may have about the risk of delaying surgery.

Risks to Reproduction, Unborn Babies and Nursing Infants

General Statement

You must not be pregnant or breastfeeding, and you should not become pregnant or breastfeed while you are taking the study treatments. Women should not breastfeed while receiving nivolumab and up to 18 weeks from the last dose of nivolumab. You must use an adequate method to avoid pregnancy for the duration of this study and for up to 23 weeks after the last dose of study drug. Male subjects who are sexually active with a woman of child bearing potential should also use an adequate method of birth control to avoid pregnancy of their partner for up to 31 weeks after the last dose of study drug. You should immediately contact your study doctor if there is a change in your method to avoid pregnancy or if you start any prescription drug or other medication (including over-the-counter drugs and herbal supplements) not prescribed by the study doctor.

Unforeseeable Risks

There may be unknown risks to you, your unborn baby or nursing infant if you are or become pregnant during this study or are breastfeeding during this study.

Human Pregnancy Outcomes
The use of nivolumab in pregnant women has not been formally studied in clinical studies. One case has been identified of a nivolumab treated male patient with a female partner who became pregnant. The pregnancy was uneventful and at birth, the infant was slightly underweight.

Occurrence of Pregnancy or Suspected Pregnancy
If you become pregnant, suspect pregnancy or if you missed your period or it is late, or if you have a change in your usual menstrual cycle (e.g., heavier bleeding during your period or bleeding between periods), you should immediately contact your study doctor.

Discontinuation from the Study
Should you become pregnant during this study, you will immediately have the study medication permanently discontinued and be referred for obstetric care You will continue to be followed for any side effects or potential benefits of the study treatment, provided it is safe for you and your unborn baby to do so. Your doctor will discuss this with you, as well as options for additional appropriate care for your cancer. The sponsor has not set aside any funds to pay for any aspects of obstetric, child or related care and does not plan to pay for them.

Pregnancy Reporting
In case of a pregnancy, your pregnancy and its outcome will be reported to the investigator/Sponsor and to Bristol-Myers Squibb

Information for Men with Partners of Childbearing Potential
Most study drugs do not pose a risk to a woman who becomes pregnant while her male partner is a study subject. However, you are asked to inform your study doctor if your partner becomes pregnant while you are enrolled in this clinical trial, and you and your partner will be asked to provide information about the pregnancy outcome. The sponsor has not set aside any funds to pay for any aspects of obstetric, child or related care and does not plan to pay for them.

Risks/Side Effects from Blood Draws
Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting is possible, although unlikely.

CT Scan
The CT scan used to measure the tumor size will expose you to some radiation. Although the radiation from each scan is within acceptable limits, these exposures add up over one's life. The amount of radiation, you will be exposed to is relatively small. Such doses of radiation may be potentially harmful, but the risks are so small that they are difficult to measure. If you have already had many x-rays, you should discuss this with the researchers before agreeing to be in the study.

A contrast dye may be used in order to help your organs show up in the scan. If used, the contrast dye will be injected into your vein to assist your study doctor and site staff in viewing the scan. One risk associated with contrast dyes include excessive scarring of the skin tissue,

joints, eyes and internal organs. Such scarring is called nephrogenic systemic fibrosis and is particularly hazardous for patients with pre-existing kidney problems. Other risks include itching or irritation at the injection site and possible allergic reactions. Your study doctor will discuss this with you.

MRI Scan

There have been no ill effects reported from exposure to the magnetism or radio waves used in this test. A known risk is that the magnet could attract certain kinds of metal. Therefore, we will carefully ask you about metal within your body (this includes certain dyes found in tattoos). If there is any question about potentially hazardous metal within your body, you will be excluded from participation in this research study. We will also keep the examining room locked so that no one carrying metal objects can enter while you are in the scanner. Please inform the study staff if you have a history of claustrophobia (extreme anxiety in close spaces). This may also be a contraindication to participation in the study.

PET Scan

During the PET scan, you will be exposed to a small amount of radiation, which is injected into the blood. Risks may include allergic reaction to the radiation injection.

Tumor Biopsy

There are risks associated with any biopsy. All biopsies will be done by physicians who specialize in collecting biopsies. The risks of biopsy can include soreness and discomfort. You may feel a stinging sensation each time the biopsy needle pierces the tumor. Serious bleeding and infection are very rare, but minor bleeding is common. Tell the study doctor immediately if the bleeding is heavy or lasts a long time. Signs of infection include pain, swelling, redness, or fever. Infection is the bloodstream (sepsis), causing high fever, is rare but serious.

Hepatitis screening

Per South Carolina law, if you test positive for Hepatitis B or C, the results of your test must be reported to the South Carolina Department of Health and Environmental Control.

Genetic Research

Genetic research studies may present unique risks to human subjects and their relatives. These involve medical, psychosocial and economic risks, such as the possible loss of confidentiality (private information), loss of insurability and employability, paternity, and social stigmas. Knowledge of one's genetic make-up may also affect one's knowledge of the disease risk status of family members. Genetic research raises difficult questions about informing you and other subjects of any results, or of future results. Some people feel anxious about the possibility of having a defective gene that would place them or their children at risk. Some people want to know what is found out about them; others do not. The risks of knowing include anxiety and other psychological distress. The risks of not knowing what is found include not being aware if there is treatment for the problem being studied. But these risks can change depending on whether there is a treatment or cure for a particular disease and on how clear the results are. If there is a medical reason to seek specific information from you, your doctor will tell you this. A

process called "genetic counseling" is often appropriate in such cases; you should ask your doctor or nurse about this if you have any questions.

South Carolina law, mandates that your genetic information obtained from any test or from this research, be kept confidential. Our state law prohibits an insurer using this information in a discriminatory manner against your or any of your family in issuing or renewing insurance coverage for you or your family. Our state law further prohibits our sharing your genetic information with anyone except in a few narrow circumstances, one of these being a research project of this type, approved by the Institutional Review Board and then we must take all steps to protect your identity. You will still be responsible for paying for health care, however. The Medical University of South Carolina will not be responsible for such costs, even if care is needed for a condition revealed during research or clinical testing.

Genetic Information Nondiscrimination Act (GINA)

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this new federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it protect you against genetic discrimination by all employers.

Loss of confidentiality

There is a risk of loss of confidentiality since medical records will be reviewed during this study.

Unknown risks

The experimental study drug may have unknown side effects. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

E. BENEFITS

If you agree to take part in this study, there may or may not be direct medical benefit to you. Your participation in this study may provide important information regarding the study drug and that may lead to future clinical studies. Other patients with cancer may benefit in the future.

F. COSTS

Examinations, scans, laboratory tests, and other medical procedures and treatments that would routinely be needed to treat and monitor your illness are known as "standard of care" services. You and/or your insurance company will be billed for the standard of care services you receive while participating in the clinical trial. You will be responsible for any co-payments, co-insurance, and deductibles that are required by your insurance plan. Some insurance plans will not pay for the standard of care services you receive while participating in a clinical trial. Please check with your insurance company to find out if your plan will pay. If your insurance plan will not pay, you will be responsible.

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The following procedures are considered standard of care and will be billed to you or your insurance company:

- Screening procedures:
  - Physical exam, vital signs, EKG
  - Tumor assessments (CT or MRI scan)
  - Blood testing looking at your blood counts, blood chemistries and how well your blood clots
  - Urinalysis
- Surgery

The following procedures are not considered standard of care and will be paid by the sponsor:

- Screening blood tests looking at your thyroid and pancreatic function and some extra blood chemistries
- On study procedures:
  - Physical exams, vitals and weight
  - Blood tests to look at blood cell counts and chemistries
  - Blood samples for research purposes
  - Tumor Assessments
- The drug nivolumab and drug administration
- Optional blood draws for genomic research study

Please ask Dr. Neskey if you would like to know more about which tests and studies are being done solely for research purposes.

G. PAYMENT TO PARTICIPANTS

You will not be paid for participating in this study. .

H. ALTERNATIVES

If you choose not to participate in this study, you could receive other treatments for your condition. The standard therapy for your condition is to proceed to surgery without nivolumab.

I. SIGNIFICANT NEW FINDINGS

If there are significant new findings during the course of the study, you will be notified.

J. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

K. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

L. CLINICAL TRIALS.GOV

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.

M. SPONSOR COMMITMENT

In the event of a study related injury, MUSC will provide medical treatment to you. MUSC will bill your insurance company, however should the insurance company deny coverage or if insurance is not available, you will be responsible for payment of services.

N. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The sponsor and the Food and Drug Administration (FDA) will receive copies of the research records. The investigators associated with this study, employees of the sponsor, the FDA, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event of a study related injury, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the

Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. The data collected on you to this point remains part of the study database and may not be removed. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Dr. Neskey at 843-792-4271. I may contact the Medical University of SC Hospital Medical Director (843) 792-9537 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

If you wish to participate, you should sign below.

Signature of Person Obtaining Consent	Date	Signature of Participant	Date