CONSENT DOCUMENT

TITLE: PREVLAR: A Phase 2a Randomized, Parallel Group, Open-Label, Multicenter Study to Assess the Safety and Efficacy of Different Schedules of RRx-001 in the Attenuation of Oral Mucositis in Patients Receiving Concomitant Chemoradiation for the Treatment of Locally Advanced Squamous Cell Carcinomas of the Oral Cavity or Oropharynx

PROTOCOL NO. PR-001

SPONSOR: EpicentRx, Inc.

INVESTIGATOR: [INSERT PI]
[ADDRESS]
[CITY, STATE, ZIP]
United States

STUDY-RELATED PHONE NUMBER(S): [INSERT PI]
[24-HOUR PHONE #]

You are being invited to take part in a research study. This consent form has information to help you decide if you want to participate. Take your time and read this consent form carefully. Ask the study doctor or study staff any questions you may have. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

You should not sign this form until you understand all of the information presented in the following pages and until all of your questions about the research have been answered to your satisfaction.

Your participation is strictly voluntary, meaning that you may or may not choose to be part of this study. If you do not want to participate, your regular medical care and legal rights will not be affected. Even if you join this study, you may stop at any time.

WHY AM I RECEIVING THIS INFORMATION?

You are being asked to take part because you have head and neck cancer for which your doctor has prescribed a chemotherapy called cisplatin that is given by intravenous (IV) infusion and radiation, which is delivered from a machine that precisely targets your tumor. The term intravenous or IV means "into the vein" or bloodstream; in this instance an IV infusion refers to the slow delivery of the chemotherapy agent cisplatin into a vein in your arm or your chest.

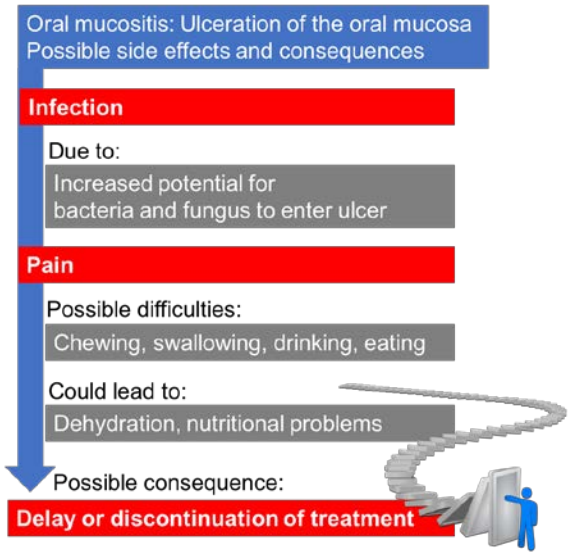
This study is being done for research. Your participation in this research study is voluntary. The purpose of this Informed Consent Form is to give you the information necessary to make an informed, voluntary choice about whether you would like to participate in this study. Any new information or knowledge, which develops during the course of this study, that may impact your

safety or your willingness to participate will be shared with you. Should you decide that you do not wish to participate in this study, you will not lose any benefits and/or access to treatment(s) to which you would have been otherwise entitled. Please read this form carefully. If you have any questions, please ask your study doctor or coordinator to explain any words or information that you do not understand. If you decide to take part in this study, you must sign your name at the end of this form and date it. No study tests can be started until you sign and date this form.

WHY IS THIS STUDY BEING DONE?

One common and unfortunate side effect of treatment with cisplatin and radiation is oral mucositis, which refers to irritation of the lining of the mouth, called the oral mucosa. Oral mucositis (OM) is a serious problem 1) because the open mouth sores from OM may trigger a Domino Effect (See Figure 1), which has the potential to lead to severe pain, nutritional problems and dehydration from an inability to eat and drink, an increased risk of infection from bacteria and fungus and delay or discontinuation of treatment and 2) because there is only one approved therapy to treat or prevent it.

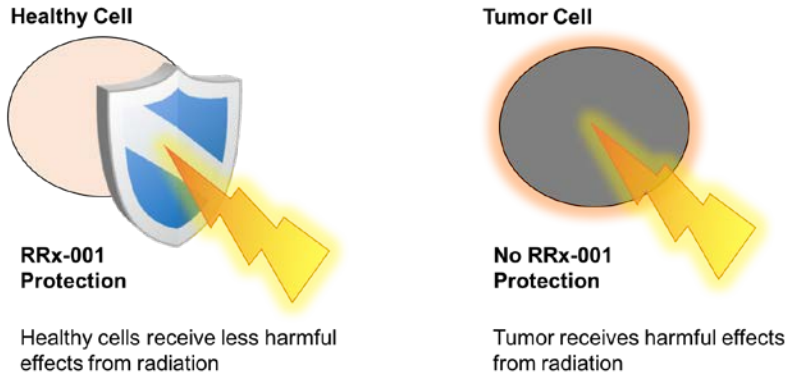
Figure 1. Domino Effect of Oral Mucositis



OM generally starts 5-10 days after treatment is started and may last anywhere from 1 week to 7 weeks or more. This study is called PREVLAR because Kevlar is a bulletproof material and the hope is that the experimental anticancer agent called RRx-001, which is added on to the cisplatin and radiation treatment, will, similar to body armor, protect the normal tissues and reduce the duration or length of severe mucositis without affecting the anticancer activity of the chemotherapy and radiation. (See Figure 2)

Figure 2. Chemoradioprotection

It is believed that the study drug RRx-001 provides a protective barrier for healthy cells to better withstand damage from radiation therapy and chemotherapy. This protection is thought not to extend to tumor cells



To date, RRx-001 has been given to over 200 patients as an anticancer agent in over 9 clinical trials. 2 of these 9 trials are in combination with chemotherapy and radiation and 1 is in combination with cisplatin. In the course of these anticancer clinical trials with RRx-001, patients appear in general to have experienced less side effects than would otherwise have been expected from chemotherapy and/or radiation alone. Also, animal experiments have demonstrated that RRx-001 is protective against the side effects or toxicities both of radiation and chemotherapy agents like cisplatin.

An agent like RRx-001 that protects normal tissues but not the tumor from the side effects of chemotherapy and radiation is called a chemoradioprotector. RRx-001 comes from the United States munitions or defense industry, where its closest chemical relative is a replacement for dynamite or TNT, (although RRx-001 is not explosive) so it is somewhat ironic or interesting that currently RRx-001 is under investigation by the United States government as a chemoradioprotector for soldiers in case of a nuclear or chemical weapons attack.

In this study, 40 patients will be randomized to 1 of 4 groups or arms. The verb "to randomize" means to put into a group by chance. The selection of patient groups or arms is made or determined randomly by a computer program (hence the word *random*ize). You will have an equal chance of being enrolled in arm 1, 2, 3, or 4. The treatments in this study are not blinded, meaning you and your study doctor will know what treatments you will receive.

All patients in this study will receive up to 7 weeks of standard of care radiation therapy given with the chemotherapy agent, cisplatin (cisplatin is given as either 40 mg/m^2 doses once every week or as 100 mg/m^2 doses on weeks 1, 4, and 7).

Patients in arms 1, 2 and 3 will also receive RRx-001 on different schedules.

The safety and how well this drug combination is tolerated will be determined. In particular, your physician or one of the research staff will examine the lining of your mouth, lips, cheeks, tongue, palate, gums and denture-bearing areas. They will check you before the first radiation treatment and then twice a week throughout the radiation therapy. After completion of the radiation therapy, you will be examined again by the research staff with a bright penlight. Changes noted will be marked on a scoring sheet.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

40 patients will take part in this study in many sites across the US.

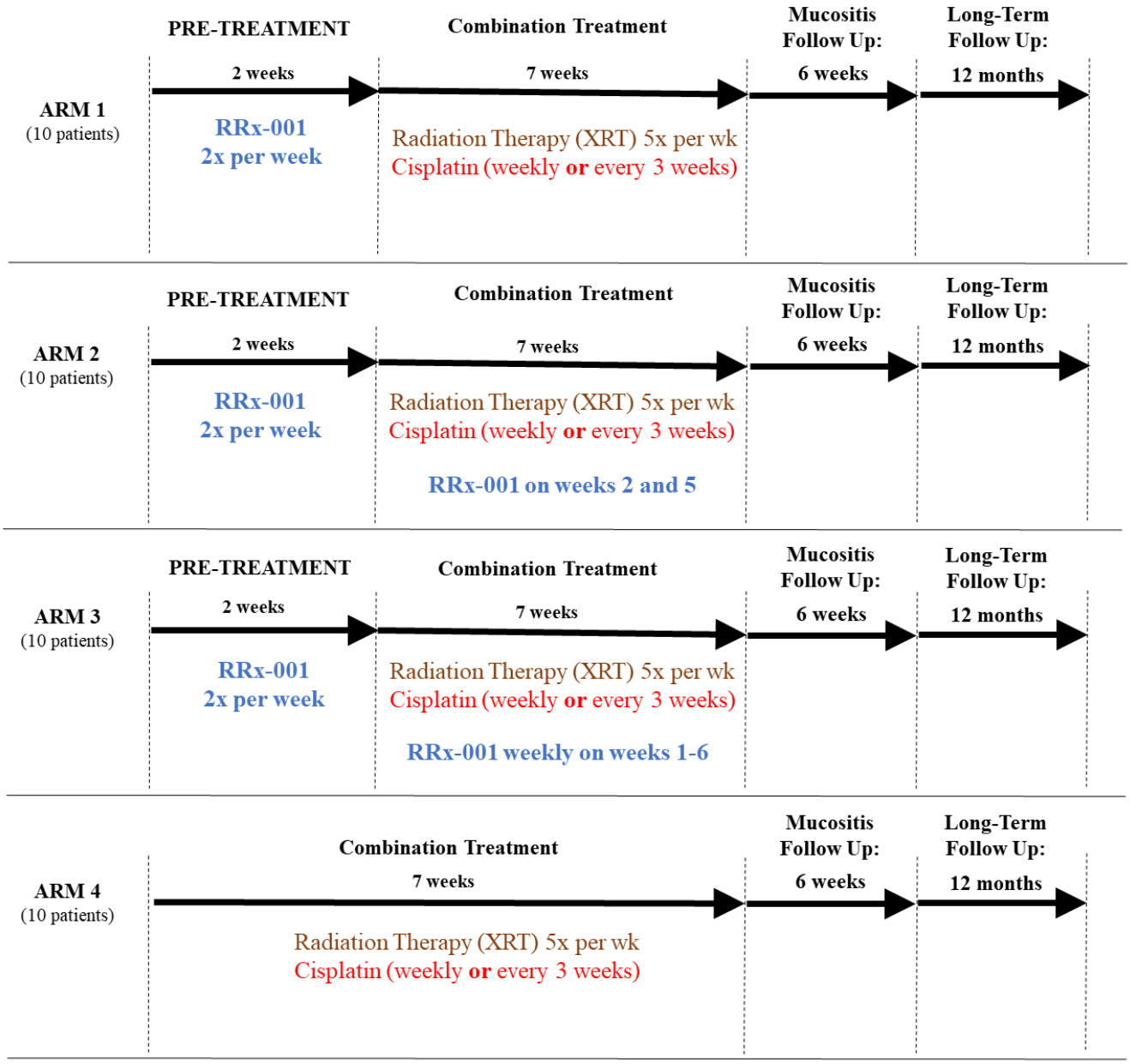
WHAT WILL I BE ASKED TO DO?

STUDY DESIGN

No matter which arm of the study you are enrolled in, the study will consist of the following four (4) periods:

- A Screening Period (Up to 28 days before receiving treatment)
- A Treatment Period, which will continue for 9 weeks, or until you develop intolerable side effects, whichever comes first.
- A Mucositis Observation Follow-Up Period, which will continue until your oral mucositis improves.
- A Long-Term Follow-Up Period. If/when you complete the treatment period, you will come to the study center for follow-up visits every 3 months for 1 year.

Figure 3. PREVLAR study schema



SCREENING PERIOD

The Screening Period will last up to 28 days. If you agree to be in this research study, you will be asked to sign this consent form before the following screening procedures are performed to determine if you are eligible for the study. These screening tests may be performed over multiple days and can take between 4 and 8 hours to complete.

- An occupational, family, social and medical history which will include questions about your cancer diagnosis and treatment as well as your health and any past or present medical problems and a review of medications, vitamins, and dietary supplements you have taken in the past or are taking now.
- Physical and dental examination
- Your physician or one of the research staff will examine the lining of your mouth, lips, cheeks, tongue, palate, gums and denture-bearing areas.
- An exam of the back of your throat called a laryngopharyngoscopy may be performed using a mirror, a small telescope, or a tube.
- Hearing test
- Measurement of your height, weight and vital signs (including sitting blood pressure, heart rate, breathing rate and temperature)
- Approximately 2 teaspoons of blood will be taken to check your overall health and the health of your organs (i.e. liver and kidneys). The blood will be collected from a vein in your arm or in your chest.
- A pregnancy test if you are female and able to get pregnant.
- You will be asked to fill out a form with questions about your oral mucositis. The form will take about 15-20 minutes to complete. The form will ask about things like your overall health, mouth and throat soreness, and diarrhea. You don't have to answer any question that makes you feel uncomfortable.
- Computed Tomography (CT) or PET/CT scan of the chest and a Computed Tomography (CT), MRI, or PET/CT scan of the tumor and neck.
    - A CT scan is an imaging procedure that uses special x-ray equipment to create detailed pictures, or scans, of the tumor. A contrast agent, usually gadolinium, is used to enhance the visibility of certain tissues. The contrast agent is given via a small intravenous (IV) line placed in a vein in your arm.
    - A positron emission tomography (PET) scan is a test that uses radioactive glucose (sugar) and a computer to create images of how organs and tissues in the body are functioning. Abnormal cells in the body use glucose at a different rate than normal cells and this allows the scanner to create a detailed picture of how your body is working.

- Magnetic resonance imaging (MRI) is a type of scan that uses magnetic fields and radio waves to make a picture of the tumor and neck.

It is possible that after the results of these tests and scans are reviewed, you will not qualify for the study. If you are ineligible, the study doctor or the study staff will discuss the reasons why you cannot take part in the study.

TREATMENT PERIOD

If the exams, tests and procedures show that you can be in the study and you choose to take part, then you will be enrolled into one of the 4 arms of this study.

RRX-001 TREATMENT

If you are enrolled in arms 1, 2 or 3, you will receive treatment with RRx-001. Whether or not you receive RRx-001, standard of care cisplatin and radiation therapy will be given. Using an investigational device called the eLOOP, RRx-001 is administered in combination with 12 milliliters (mLs) of blood (2.4 teaspoons) drawn up from your veins and mixed gently with 4 mg of RRx-001 before being given back to you through a vein in your arm or your neck or chest over a period of approximately 30 minutes.

Before treatment with RRx-001, a pre-medication such as dexamethasone, a corticosteroid, will be given to help with any pain associated with the infusion. Based on recent clinical experience with the blood administration of RRx-001, pain during infusion is possible.

CISPLATIN TREATMENT

You will receive one of the following cisplatin treatment schedules:

(1) 40 mg/m^2 of intravenous cisplatin 1 day per week for up to 7 weeks for a total of up to 7 doses.

or

(2) 100 mg/m^2 of intravenous cisplatin 1 day per week on weeks 1, 4 & 7 for a total of 3 doses.

RADIATION THERAPY

You will receive radiation therapy on days 1-5 of each week for up to 7 weeks.

OTHER STUDY ASSESSMENTS

Listed below are exams, tests, and procedures that need to be done as part of this study to monitor your safety and health but may not be included in the usual care. We will use them to carefully follow the effects of the study treatment, including preventing and managing side effects.

These exams, tests, and procedures to monitor your safety and health include:

- Physical examination done weekly during the Treatment Period and Mucositis Observation Follow-up Period, and at the end of treatment visit.
- Measurement of your height, weight and vital signs (including sitting blood pressure, heart rate, breathing rate and temperature) done weekly during treatment.
- Approximately 2 teaspoons of blood will be taken to check your overall health and the health of your organs (i.e. liver and kidneys). The blood will be collected from a vein in your arm or in your chest weekly during treatment and at the end of treatment visit.
- CT, PET/CT, or MRI scans will be done during follow-up according to your study doctor's recommendations. Please ask your study doctor about scheduling these scans.

Some exams, tests, and procedures are a necessary part of the research study but would not be included in usual care. Listed below are procedures that will be done for research purposes only.

- Your physician or one of the research staff will examine the lining of your mouth, lips, cheeks, tongue, palate, gums and denture-bearing areas.
- You will be asked to fill out a form with questions about your oral mucositis. You will be asked to fill out this form every day during the cisplatin and radiation therapy treatment. If you are still experiencing symptoms of oral mucositis at the end of treatment, the form will need to be filled out during the mucositis observation follow-up period as well. Each form will take about 15-20 minutes to complete. The form will ask about things like your overall health, mouth and throat soreness, and diarrhea. You don't have to answer any question that makes you feel uncomfortable.
- An exam of the back of your throat called a laryngopharyngoscopy may be performed using a mirror, a small telescope, or a tube. This exam may be performed during the mucositis observation follow-up period, at the end of treatment visit and every 3 months during long-term follow-up.

HOW LONG WILL I BE IN THE STUDY?

You can remain on study about 9 weeks, provided your tumor doesn't get worse and you don't experience side effects that prevent you from continuing the treatment. After you are finished taking the treatments, you will have follow-up visits every 3 months for 1 year. Your doctor may decide to take you off this study if your mucositis becomes worse, if other side effects become very severe, if new scientific developments occur that indicate this research study is not in your best interest, if your physician feels that this study is no longer in your best interest or the sponsor may withdraw support for the study.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first. There are no known serious consequences of sudden withdrawal from the study. Your cisplatin and radiation therapy may be continued to completion if medically appropriate.

WHAT RISKS AND SIDE EFFECTS ARE EXPECTED FROM THE STUDY?

Participation in this study may involve some added risks or discomforts. While you are on this study, you are at risk for the side effects listed below. You should discuss these with your doctor. There may also be other side effects that we cannot predict. Other drugs will be given to make side effects less serious and uncomfortable. Many side effects go away shortly after the study drug is stopped, but in some cases, side effects may be serious, long lasting, and may even cause death.

There may be other risks associated with participation in this study that are currently unforeseeable. The addition of RRx-001 to cisplatin and radiation may increase or decrease the effectiveness of radiation therapy on your cancer, and it may also increase or decrease the side effects of cisplatin and radiation on normal tissue in treatment area.

RISKS ASSOCIATED WITH RRX-001

In the initial clinical trial of RRx-001 in which 25 patients with various different types of cancers received RRx-001 intravenously, the main side effect in 84% of patients was temporary pain and/or a stinging, burning sensation at the injection site in the forearm and along the length of the vein as well as swollen veins (vasodilation). Pain and swollen veins, when they occurred, lasted during the entire time of infusion of RRx-001 and, generally, both of these side effects went away almost immediately (within minutes) of stopping the infusion of RRx-001.

This discomfort experienced by patients during infusion was when the drug was injected directly into a vein and now the administration process has been updated to mix with blood prior to infusion, eliminating all or most of the discomfort associated with direct IV infusion. However, in most patients that have received blood mix, mild side effects related to the IV infusion such as pain, itching, flushing, chest tightness and cough may be present. To minimize the risk of discomfort, you will receive an anti-inflammatory medication (corticosteroid) before the infusion. Your study doctor may also slow down the infusion.

Side Effects Related to RRx-001	
Common (occurring in 10% or more of patients)	• Swelling and redness in the arm or site of the medication injection • Vein hardening • Shortness of breath • Mouth tingling/burning • Anxiety • Chest discomfort • Cough • Fatigue • Skin discoloration
Less common (less than 10% of patients)	• Flushing • Throat discomfort • Vein swelling (vasodilation) • Vein blockage • Weakness • Pain • Bleeding of the tumor • Constipation • Redness and pain around the mouth and lips • Diarrhea • Anemia, which may cause tiredness, or may require blood transfusion • Loss of appetite • Dry skin • Rash • Stroke • Clostridium difficile colitis (an infection of the colon). The symptoms of C. difficile colitis include fever, diarrhea, and abdominal pain.
Rare (less than 1% of patients)	• Abdominal pain • Hand numbness • Bloody mucus • Decreased respirations • Dizziness • High blood pressure • Discomfort in the nose • Runny nose • Involuntary leakage of urine • Vision changes • Vomiting

There were no serious side effects that were thought to be related to RRx-001 during the initial study which were life-threatening or required hospitalization of the patient.

During a recent study of RRx-001 in combination with irinotecan, an FDA-approved anticancer agent, one RRx-001-treated patient died on study due to low blood counts and infection (sepsis); which can occur with irinotecan. While it is unlikely that RRx-001 contributed to these side effects, based on its overall favorable safety track record, it is also impossible to definitely rule it out since

this was the first such treated patient. It is also important to note that by choosing to participate in this study, you will not be receiving combination therapy with RRx-001 plus irinotecan.

Because to date less than 300 patients have received RRx-001, it is possible that not all of the side effects are known at this time especially in combination with cisplatin and radiation. Also, it is important to be aware that, even though precautions and prevention practices are in place, treatment of your blood with RRx-001 outside of the body before it is returned to you is a risk factor for bacterial contamination of the blood. The administration of contaminated blood may possibly lead to life threatening or fatal infections. For this reason, you will be watched closely for known and other unknown, possibly serious side effects.

RISKS ASSOCIATED WITH RADIATION TO THE HEAD & NECK:

Risks and side effects related to radiation therapy		
Likely	• Sores in the mouth and/or throat which can be painful and make it very difficult to chew and or swallow foods • Mouth dryness or changes in taste and/or smell that may be permanent • Thick saliva • Hoarseness	• Tanning or redness of the skin in the head and neck area being treated with radiation • Ear pain and/or pressure • Fatigue • Weight loss • Permanent hair loss in the area treated with radiation • Loss of teeth, or cavities in the teeth, if strict dental care is not followed and/or hypersensitivity of teeth
Less Likely	• Decrease in function of the thyroid gland that may require you to take thyroid replacement medicine to prevent you from feeling tired or sleepy • Serious damage to the spinal cord, nerves in the neck, jawbone, voice box, skin, or other parts of the head and neck that may require a major operation to correct and, rarely, can even be life threatening • Temporary pain or scarring around nerves in the shoulder that could cause numbness and/or weakness	• Breathing problems • Difficulty with swallowing and eating for which you might need a long term or permanent feeding tube; possibility of inhaling food and/or liquids into the lungs – which could also result in pneumonia • Serious ear infections and/or hearing loss • Damage to the spinal cord leading to permanent weakness and/or symptoms like a "stroke" • Permanent hair loss (of the face/chin/neck)

RISKS ASSOCIATED WITH CISPLATIN:

Risks and side effects related to cisplatin		
Likely	• Decrease in blood counts that may cause infection, bleeding, and bruising • Loss of appetite	• Nausea and vomiting • Hearing loss or ringing in the ears • Numbness or tingling in the hands or feet

Risks and side effects related to cisplatin		
Less Likely	• Muscle cramps or spasms • Loss of coordination • Involuntary movements or shaking • Rash • Vision problems	• Hair loss • Low mineral levels in your blood • Decrease in liver function causing temporary elevation in blood tests • Metallic taste
Rare, but serious	• Loss of muscle or nerve function, which may cause weakness or numbness in your hands and feet • Decreasing ability of the kidneys to handle the body's waste, which may be permanent	• Allergic reactions, which can cause difficulty in breathing, fast heartbeat, and sweating • Secondary cancers

RISKS ASSOCIATED WITH DEXAMETHASONE OR OTHER CORTICOSTEROIDS:

Side Effects Related to Dexamethasone or other corticosteroids	
Common (occurring in 10% or more of patients)	• Edema (fluid retention) • High blood pressure • Sodium (salt) retention (build up) and/or potassium loss. Sodium and potassium are referred to as electrolytes. In the case of sodium build up symptoms may cause swelling due to water retention while potassium loss may cause symptoms such as cramps, weakness and heart palpitations (skipped heartbeats) • Increased appetite and weight gain • Extreme mood swings • Tiredness • Depression • Inability to sleep • Nausea/vomiting
Less common (less than 10% of patients)	• Increased sweating, • Increased blood sugar, which may cause damage to your blood vessels and/or increase your risk of having diabetes. Symptoms of diabetes include increased thirst, dry mouth and increased need to urinate or pee. • Irregularities in the menstrual cycle (periods) • Excess hair • Thinning of bone • Increased risk of infections • Hiccups • Abdominal pain • Stomach ulcers (sores) • Skin disorders
Rare (less than 1% of patients)	• Patients with pre-existing schizophrenia and/or epilepsy may experience worsening of their disease • Patients with heart disease may experience heart failure

OTHER STUDY-RELATED RISKS

***Allergic Reactions*:** As with any drug, there is the chance of an allergic reaction, which may include difficulty breathing, rash, flushing, weakness, dizziness, lightheadedness, and swelling. Please contact the study doctor immediately if you experience any of these symptoms. Severe allergic reactions can be life-threatening.

Intravenous (IV) Injection Side Effects: If the drug leaks from the vein the shot is given into, it may cause skin irritation at the needle site.

Risks of Blood Draws: There is a risk of discomfort or pain, bleeding, swelling and a small arm bruise and swelling when blood is drawn. Rarely, a clot or infection may occur at the site of the blood draw. Some people also become faint, dizzy, or light-headed during or immediately after the blood draw.

Risks and Side Effects of a Central Line: Patients may be required to have placement of a "central line." A central line is a catheter that is placed under your skin and into a large vein. It will allow easy administration of the chemotherapy drugs. Risks of placement of a central line include bleeding or lung collapse when the catheter is placed, as well as inflammation at the site of the catheter, and infection.

Reproductive Risks: You should not become pregnant or father a baby while on this study and for a period of time following your last dose of RRx-001 because the drugs in this study can possibly affect a fetus and cause serious birth defects. Women should not breastfeed a baby while on this study. It is important you understand that you need to use birth control while on this study. If you are female and capable of childbearing, a pregnancy test will be done before the study to be sure as possible that you are not pregnant. Your participation requires that you use adequate contraception (hormonal or non-hormonal (such as abstinence, diaphragm, condom, or intrauterine device) contraception methods to prevent pregnancy for the duration of the study and for 90 days following your last dose of RRx-001. Ask about counseling and more information about preventing pregnancy.

Risks of MRI: Some people cannot have an MRI because they have some type of metal in their body. For instance, if you have a heart pacemaker, artificial heart valves, metal implants such as metal ear implants, bullet pieces, chemotherapy or insulin pumps or any other metal such as metal clips or rings, you cannot have an MRI. During this test, you will lie in a small closed area inside a large magnetic tube. Some people are scared or anxious in small places (claustrophobic). The MRI scanner makes loud banging noises while taking a measurement, so either ear plugs or specially designed headphones will be used to reduce the noise.

Risks from CT scans: Procedures such as CT scans will be used during this research study to see how you are doing. The cumulative radiation exposure from these tests is considered small and is not likely to adversely affect you or your disease. However, the effects of radiation add up over a lifetime. It is possible that having several of these tests may add to your risk of injury or disease.

When deciding to enter this study, think about your past and future contact with radiation. Examples of contact with radiation include x-rays taken for any reason or radiation therapy for cancer treatment.

Risks of IV Contrast: As part of this study a CT scan may be done. There may be some reactions related to the contrast dye used in CT scans. Contrast dye is usually administered when you get a CT scan. Some people may develop hives and itching or other allergic symptoms from this dye, swelling of the heart, cramps of the voice box, breathing distress caused by narrowing of the airways in lungs, low blood pressure, with loss of consciousness, and in rare cases, severe loss of blood and fluids leading to shock and death, fainting, seizures, and irregular heartbeats. In addition, if you have low kidney function, this dye can temporarily or permanently decrease your kidney function.

Risks of Loss of Confidential Information: There is also a small risk that information from your health records will be released to an unauthorized party. We will do our best to make sure that your personal information will be kept private. The chance that this information will be given to someone else is very small. An identification code assigned by the study team to each patient will be used in place of your name to protect your identity when reporting trial-related data.

ARE THERE ANY BENEFITS FOR ME IF I CHOOSE TO TAKE PART IN THIS RESEARCH STUDY?

If you agree to take part in this study, there may not be direct medical benefit to you. Others, however, may benefit from the information learned from this research study, and the investigators may learn more about RRx-001.

WHAT ARE MY OPTIONS IF I AM NOT IN THE STUDY?

If you choose not to take part in or stop participating in this research study, there may be other treatments. Refusal to take part in this study will not cause penalty or loss of benefits to which you are otherwise entitled.

You do not have to participate in this study to receive treatment for your cancer or your mucositis. Other possible treatments could include treatment with other drugs or drug combinations, participation in other research studies, or supportive care only (no cancer treatment). You can receive cisplatin and radiation therapy without participating in this study. Please talk to your doctor about these and other options.

HOW WILL I KNOW IF NEW INFORMATION IS LEARNED THAT MAY AFFECT WHETHER I AM WILLING TO STAY IN THIS RESEARCH STUDY?

During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

WILL I BE PAID TO TAKE PART IN THIS STUDY?

You will not be paid to take part in this research study.

The study drug, RRx-001, will be supplied at no cost while you take part in this study. The cost of getting the study drug, RRx-001, ready is also provided at no cost. The study drug administration is not paid for by the study sponsor, so you or your health plan/insurance company may have to pay for this. It is possible the study drug, RRx-001, may not continue to be supplied while you are on the study. Although not likely, if this occurs, your study doctor will talk to you about your options.

WILL THERE BE A COST TO ME TO PARTICIPATE IN THIS RESEARCH STUDY?

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

Examples of procedures and drugs that may be billed include the following: routine clinic visits, routine laboratory tests, CT imaging, pre-medications (dexamethasone), and FDA-approved chemotherapy with cisplatin and radiotherapy.

There will be no payment to you for participating in this study.

The sponsor, EpicentRx, Inc., is paying the institution, [INSERT SITE] to do this study.

WHAT WILL HAPPEN IF I AM INJURED DURING THIS STUDY?

If you think you have been harmed by participation in this study, tell the study doctor and seek medical attention immediately. Reimbursement will be made for any reasonable and necessary medical expenses incurred by you as a direct result of the study drug (as determined by medical professionals), or medical procedures required by the study. Financial compensation for such things as lost wages, disability or discomfort due to a study related injury is not available. You

will not give up any legal rights by signing this form. You must follow the directions of the study doctor to be eligible for this coverage.

WHAT IF I CHOOSE TO WITHDRAW FROM THE STUDY?

Participation in this study is entirely voluntary. If you choose not to participate or wish to withdraw your consent to participate in these study procedures at any time, it will in no way affect your regular treatments or medical care at this institution or loss of benefits to which you are entitled.

You will be informed of any new findings that might affect your willingness to continue participating in the study.

The study doctor may stop your participation in this study without your consent. If you have any side effects that are very serious or if you become ill during the course of the research study you may have to drop out even if you would like to continue. The study doctor will make the decision and let you know if it is not possible for you to continue. The decision that is made is to protect your health and safety, or because it is part of the research plan that people who develop certain conditions or do not follow the instructions from the study doctor may not continue to participate. In addition, EpicentRx, Inc., may end your participation in the study at any time without your consent.

If you withdraw from the study for any reason, you must notify your study doctor, [INSERT PI] at (xxx) xxx-xxxx. You will be asked to return to the clinic so that the study doctor may perform a final evaluation, which includes laboratory tests. Additional details can be found in the Procedures section of this document.

HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE OR CONFIDENTIAL?

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

Your personal information may be given out if required by law.

Information about your cancer and treatment will be collected from your medical record for the study. The information will be with a study identification number and stored in a secured electronic file. The electronic file is password protected and accessible only to authorized study personnel.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

PERMISSION (Authorization) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

Information about you and your health is personal and private, so this information generally cannot be used in this research study without your written permission. The next few paragraphs tell you about how researchers want to use and share your health information in this research study. Your information will only be used as described here or as allowed or required by law. Ask questions if you do not understand any part of the research or the use of your health information. If you sign this consent form, you agree to let the researchers use your information in the research and share it with others as described below.

What is the purpose of this research study and how will my health information be utilized in the study?
You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help researchers answer the questions that are being asked in the research.

What information about me will be used?
If you choose to be in this study, the study doctor will get your personal and medical information. This information may include:

- All information in your medical record
- Hospital discharge summaries
- Radiology records or images (MRI, CT, PET scans)
- Medical history or treatment
- Medications
- Consultations
- Laboratory/diagnostic tests or imaging
- EKG and/or EEG reports
- Quality of life questionnaires
- Pathology reports, specimen(s) or slide(s)
- Operative reports (about a surgery)
- Research records

Who may use, share or receive my information?
The research team may use or share your information collected or created for this study with the following people and institutions:

- [INSERT SITE] researchers involved in the study;
- [INSERT IRB]
- Members of the research team, including the study doctors, research nurses and study coordinators

- The study Sponsor, and those working for or with the Sponsor, which may include affiliates of the Sponsor located in your country or other countries. An affiliate of the Sponsor includes all companies directly or indirectly owned by EpicentRx, Inc.
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- The U.S. Food and Drug Administration (FDA)
- Members of the company monitoring the study

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review my research record while the research is ongoing?
No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I have to give my permission?
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this research study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say yes now, can I change my mind and take away my permission later?
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes but change your mind later for the use of your information in the research, you must write to the researcher and tell him or her of your decision:

[INSERT PI]
[ADDRESS]
[CITY, STATE, ZIP]

How long will my permission last?
There is no set date when your permission will end. Your health information may be studied for many years.

Where can you get more information?
You may call the National Cancer Institute's Cancer Information Service at:

Voice: 1-800-4-CANCER (1-800-422-6237)

You may also visit the NCI Web site at http://cancer.gov/
For NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials/
For NCI's general information about cancer, go to http://cancer.gov/cancerinfo/

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who can I call if I have questions?

The study doctor or study staff will answer any questions you have about this research study or your participation in the study. You can ask questions any time during the study. Please call if you have any questions, concerns or complaints about the study or your experience in the study, or if at any time you feel you have experienced a research-related injury.

[INSERT PI]
[TELEPHONE #]

If you have questions about your rights as a research subject or if you have questions, concerns, or complaints about the research, you may contact:

[INSERT IRB]
[ADDRESS]
[CITY, STATE, ZIP]
[TELEPHONE # (if applicable)]
[EMAIL (if applicable)]

[INSERT IRB] is a group of people who perform independent review of research. [INSERT IRB] will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact [INSERT IRB] if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

AGREEMENT TO PARTICIPATE

Subject consent:

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

I agree to take part in this study.

Subject Name:_____

Subject Signature:_____ Date: _____

Witness Name:_____
(*When applicable, using short form)*

Witness Signature:_____ Date: _____
(*When applicable*)

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject have been accurately answered.

Investigator/Person Obtaining Consent:_____

Signature:_____ Date: _____