UNIVERSITY OF CINCINNATI - Medical
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: A Phase I/ II Study of chemo radiation plus the Anti-PD-1 Antibody, Pembrolizumab (MK-3475) for Locally Advanced Laryngeal Squamous Cell Carcinoma

UC IRB Study #: 2015-8190 **Sponsor Name:** Investigator-Initiated

Investigator Information:

Vinita Takiar, MD	513-584-7698	513-584-7661
Principal Investigator Name	Telephone Number	24 hr Emergency Contact

Subject Name: _____ Date of Birth: _____/_____/____

INTRODUCTION:

A biomedical or health-related research study is performed to answer specific questions about a disease.

Before you agree to participate in this research study, it is important that you be told the purpose, procedures, benefits, risks, discomforts, and precautions of the research. You should also be told what alternative procedures are available to you if you do not participate in the research study. The informed consent document is a written summary of this information. Be sure to ask questions while you read this consent document and ask questions if there is anything that you do not understand.

Your participation in this research study is entirely voluntary.

You may choose either to take part or not to take part in this research study. If you decide to take part, you may decide to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you.

The researcher and sponsor of this study do not promise that you will receive any benefits from this study.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research study is to test the safety and the benefit of adding pembrolizumab to treatment that you will already be getting for your cancer. Pembrolizumab is a therapy that activates your immune system to fight your cancer.

You will be offered “standard of care” treatment whether you participate in this study or not. The standard of care treatment will include radiation for 7 weeks in combination with chemotherapy (cisplatin) as standard of care once every 3 weeks. The risks and benefits

of the standard of care treatment will be discussed by your regular doctor.

Pembrolizumab, which is approved in the USA and some other countries, is available by prescription to treat several different cancers, but may not be approved to treat your type of cancer.

Pembrolizumab works by helping your immune system to fight your cancer.

However, pembrolizumab can also cause your immune system to attack normal organs and tissues in your body and can affect the way they work, which can result in side effects that may become serious or life-threatening, and in some cases, may lead to death.

Pembrolizumab is a medication that is currently approved by the FDA for use in some types of cancers as well as being tested in multiple other cancers. It works by turning on your immune system to recognize and fight your cancer. Pembrolizumab is already approved for treatment of melanoma. It has not yet been approved to be used in combination with chemotherapy and radiation or for head and neck cancer. However, early studies used pembrolizumab in head and neck cancer with very encouraging results. These studies are ongoing. Research in animals also suggests that pembrolizumab will help improve the effectiveness of standard of care treatment. Overall, patients tolerate this medication well.

WHY HAVE YOU BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You are being asked to take part in this research study because you are at least 18 years of age and you have head and neck cancer that requires radiation and chemotherapy.

The study doctor will determine if you are eligible for participation in this study on a case by case basis.

HOW LONG WILL YOU BE IN THE RESEARCH STUDY?

You will receive treatment with pembrolizumab for 1 dose approximately 3 weeks prior to beginning of radiation and chemotherapy. After radiation and chemotherapy begin, you will be given pembrolizumab every 3 weeks during radiation and it will continue until after you finish radiation and chemotherapy treatment.

You will be followed by the research team for 2 years after completion of the study treatment, in addition to your regular follow up care.

The researcher may decide to take you off this research study if you experience severe side effects, your cancer recurs, if drug supply is insufficient, or new information becomes available.

You may withdraw from the study at any time. If you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first so that

stopping can be done safely. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful to you.

You may be contacted in the future by representatives of the University of Cincinnati who are interested in asking you survey questions about your participation in this research study. If you choose to participate in the survey, your responses will be used for quality assurance purposes only.

WHO IS CONDUCTING THE RESEARCH STUDY?

The study is directed by Vinita Takiar, MD a medical oncologist and researcher at The University of Cincinnati, the researcher at University of Cincinnati and the facilities of the affiliated health system located at UCMC and UCPC, including West Chester Hospital.

The study drug will be provided by Merck, Sharp and Dohme Corp.

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?

About 47 people will take part in this study at the University of Cincinnati and collaborating sites across the country. About 15 will participate at the University of Cincinnati.

WHAT IS INVOLVED IN THE RESEARCH STUDY?

You will be asked to read and sign this consent before any study-specific tests or procedures are performed. If you wish to participate in this study, the following tests and procedures will be performed to find out if you can participate in the study.

Screening Visit:

- A medical history will be obtained from you to make sure you do not have any conditions or past treatments that could interfere with your taking part in this study.
- Samples of your tumor (that have already been removed by surgery or biopsy) will be obtained for testing. This may allow us to understand how the treatment works on your tumor.
- A review of the medications you are taking, including prescriptions for conditions as high blood pressure, diabetes, or allergies and non-prescription medications as vitamins, herbal supplements, aspirin, etc. will be done.
- Physical examination will be performed.
- Measurement of your weight, height, blood pressure, respiratory rate and temperature will be done.
- Either a CT scan of your neck and chest and/or a PET/CT will be performed to evaluate your tumor before treatment is started. You may already have this done by your regular doctor.
- In women able to have children, a pregnancy test will be done. The results of the pregnancy test must be negative for you to participate in this study.
- Blood sample will be taken (approx. 1-2 tablespoons) for laboratory tests and

research to help understand how treatment works on your body and tumor.

Treatment

You will receive treatment for a total of 10 weeks including before and during chemotherapy and radiation. It may be longer if additional breaks are needed. You will be given the pembrolizumab infusion around 3 weeks before radiation and chemotherapy begin. You will continue the pembrolizumab every 3 weeks for a total of 4 doses. You will receive your normal required treatment with radiation and cisplatin chemotherapy.

You will receive treatment in this study as follows:

- Study medication (pembrolizumab): You will receive your first pembrolizumab infusion approximately 21 days before radiation begins and then every 3 weeks.
- You will receive radiation every day, 5 days a week (details will be given by your radiation oncologist as part of your normal treatment).
- Chemotherapy (cisplatin): You will receive cisplatin once every 3 weeks through a vein in your arm or a PORT-a-cath in your chest (this will be described in detail by your regular doctor as part of your normal treatment).

Please see the following chart for your medication regimen:

Drug or radiation	Day -21	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7
Pembrolizumab (A)	A	A			A			A
Cisplatin (B)		B			B			B
Radiation(C) (M-F only)		C	C	C	C	C	C	C

We recommend that your surgeon (ear, nose, throat doctor) examines you approximately 3 weeks after your first dose of pembrolizumab. He/she will be evaluating the size of tumor and its appearance, and will perform a biopsy if it can be safety done and if you agree with that.

There will be additional laboratory tests and blood draws during the course of treatment to attempt to understand how the body and tumor are affected by the combination of treatment. The following tests will also be done:

- Blood samples will be taken to understand how your body, especially your immune system, reacts to the pembrolizumab and the chemotherapy (cisplatin) and radiation. Blood will be collected as follows:
    - Screening – Two tablespoons of your blood will be drawn at screening.
    - After first dose of pembrolizumab- Two tablespoons of your blood will be drawn before 1st cisplatin dose and before radiation. This will be approximately 3 weeks after first dose of pembrolizumab.

- After completion of treatment– Two tablespoons of your blood will be withdrawn approximately 3 months after completion of radiation and cisplatin treatment.

- During your clinical visits:
  - You will be asked questions about side effects and health concerns to evaluate if you are doing well with the treatment or if you are having side effects.
  - Blood samples will be taken (approx. 1 tablespoon) to make sure you are not having side effects from either your normal treatment or from the pembrolizumab.
  - A review of the medications you are taking, including prescriptions for conditions as high blood pressure, diabetes, or allergies and non-prescription medications as vitamins, herbal supplements, aspirin, etc.
  - A physical exam will be performed.
  - Measurement of your weight, height, blood pressure, respiratory rate and temperature.

All the blood draws will take place in the infusion center location where you receive your treatment as well. The standard labs needed before your standard chemotherapy may be incorporated at the same time instead of having extra blood draws.

Follow-Up:

- Follow-up will not be any different for this study than your normal follow-up with the exception of an end of study visit if you withdrawal early. The end of study visit will be similar to your regular clinic visits. You may be asked additional questions relating to the research during your follow-up.

WHAT ARE YOUR RESPONSIBILITIES IF YOU PARTICIPATE IN THIS STUDY?

You will be responsible for coming to the researcher's office or hospital throughout the treatment period and follow-up period of the study.

You will be asked not to participate in any other clinical research studies taking another investigational medicine during this study.

You will have to inform your health provider and research team about your medications or any herbal supplements. We may ask you to choose alternative medications with no or minimal suppression of the study drug activity or toxicity.

WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. There may be unknown or unforeseen risks associated with study participation. Side effects may be mild or very serious.

You should talk to your study doctor about any side effects that you have while taking part in the study.

Risks and side effects include:

Possible Side Effects of Pembrolizumab

VERY COMMON, SOME MAY BE SERIOUS In 100 people receiving pembrolizumab, 20 or more people may have the following:
• Cough • Itching of the skin • Loose or watery stools

COMMON, SOME MAY BE SERIOUS **(i.e. causing hospitalization, life-threatening, or where noted, may cause death)** In 100 people receiving pembrolizumab, at least 5 but less than 20 people may have the following:
• Joint pain • Fever • Back pain • Rash • Pain in your belly • Loss of skin color • Not enough thyroid hormone so you may feel tired, gain weight, feel cold, have infrequent or hard stools • Low levels of salt in the blood that may cause you to feel tired, confused, have a headache, muscle cramps and/or feel sick to your stomach

UNCOMMON, SOME MAY BE SERIOUS In 100 people receiving pembrolizumab, at least 1 but less than 5 people may have the following:
• Inflammation of the lungs so you may feel short of breath and cough. Sometimes this might lead to death • Too much thyroid hormone so you may feel anxious, angry, have trouble sleeping, weak, tremble, sweat, feel tired, have loose or watery stools • Inflammation of the bowels/gut that may cause pain in your belly with loose or watery stools, and black, tarry, sticky stools or stools with blood or mucus • Inflammation of the skin so you may have peeling of the skin, itching, skin redness. The skin inflammation (i.e. peeling, itching and redness) could also be widespread throughout your body. More severe skin reactions may involve the inside of your mouth, the surface of your eye and genital areas, and/or may cause the top layer of your skin to peel from all over your body which can cause severe infection. These severe conditions can sometimes lead to death. • Infusion reaction, where you may feel dizzy or faint, flushed, get a rash, have a fever, feel short of breath at the time of receiving your infusion (IV) or just after,

UNCOMMON, SOME MAY BE SERIOUS In 100 people receiving pembrolizumab, at least 1 but less than 5 people may have the following:
or pain at the site of infusion

RARE, SOME MAY BE SERIOUS In 100 people receiving pembrolizumab, less than 1 person may have the following:
• • Inflammation of the nerves that may cause pain, weakness or tingling in yourhands and feet, and may spread to your legs, arms and upper body leading to severe muscle weakness and possible temporary paralysis • Inflammation of the muscles so you may feel weak or have pain in your muscles • Inflammation of the pancreas (a gland in your abdomen that controls sugar levels) so you may have severe pain in the top part of your belly that may move to your back, feel sick to your stomach, and/or have vomiting that gets worse when you eat • Inflammation of the eye so you may have redness of the eyeeye redness, blurred vision, sensitive sensitivity to light, have eye pain, and/or see floaters or have headaches • Inflammation of the liver that may make you feel sick to your stomach and vomit, feel like not eating, cause a poor appetite, feeling tired, have a mild fever, have a pain in the right side of your belly muscle or joint aches, sick to your stomach and vomiting, pain in your belly, yellow eyes and skin, and dark urine • Inflammation of the pituitary gland (a gland in the head), which may cause you to feel sick to your stomach or have headaches, sick to your stomach, changes in your behavior, double vision, few to no menstrual cycles, weakness, vomiting and dizziness or fainting • Adrenal glands (glands on top of the kidneys) where you may not make enough hormone, which could cause tiredness, weight loss, muscle weakness, feeling faint, joint, muscle and belly aches, nausea, vomiting, loose or watery stools, fever, salt craving, and sometimes darkening of the skin like a suntan • Type 1 Diabetes, a condition that can cause too much sugar in your blood, feeling thirstier than usual, frequent urination and weight loss. You are likely to need regular insulin shots. Too much sugar in your blood (diabetes), so you may feel thirsty, and are likely to need regular insulin shots • Inflammation of the kidney so you may pass less urine or have cloudy or bloody urine, swelling and low back pain • Inflammation of the middle layer of your heart wall (myocarditis) that may cause your heart to have difficulty pumping blood throughout your body, which can cause chest pain, shortness of breath and swelling of the legs. You may experience a fast or irregular heartbeat that may cause dizziness or fainting. Sometimes this condition can lead to death • Inflammation of the thyroid gland, an organ that makes and stores thyroid hormones. This condition may lead to change in your heart rate, blood pressure,

RARE, SOME MAY BE SERIOUS In 100 people receiving pembrolizumab, less than 1 person may have the following:
body temperature, and the rate at which food is converted into energy. • A condition that may make you feel weak and tired and might have drooping of the eyelids, blurred or double vision, difficulty swallowing, slurred speech, weakness in your arms and legs, or difficulty breathing • The formation of small clusters of immune cells (called granulomas) in parts of your body such as your lymph nodes, eyes, skin, or lungs • Inflammation of the brain with confusion and fever. This may also include: disorientation, memory problems, seizures (fits), changes in personality and behavior, difficulty speaking, weakness or loss of movement in some parts of your body, and loss of consciousness • Stevens-Johnson Syndrome (SJS), a life-threatening disorder of your skin and mucous membranes. It's usually a reaction to a medication or an infection. Often, it begins with flu-like symptoms, peeling skin, fever, body aches, a flat red rash, and blisters and sores on the mucous membranes. • Toxic Epidermal Necrolysis (TEN), life-threatening skin disease that cause rash, skin peeling, and sores on the mucous membranes. • Immune-mediated myocarditis, inflammation of the heart muscle, which can be life-threatening.

COMMON IMMUNE-MEDIATED, SOME MAY BE SERIOUS In 100 people receiving pembrolizumab, less than 10 may have one of these side effects:
• Pneumonitis (inflammation of lung) • Colitis (inflammation of large bowel) • Hepatitis (inflammation of liver) which may cause a poor appetite, feeling tired, mild fever, muscle or joint aches, sick to your stomach and vomiting, pain in your belly, yellow eyes and skin, dark urine • Hypophysitis (inflammation of pituitary gland) which may cause headaches, sick to your stomach, changes in behavior, double vision, few to no menstrual cycles, weakness, vomiting and dizziness or fainting • Nephritis (inflammation of kidney) so you may pass less urine or have cloudy or bloody urine, swelling and low back pain

For immune-mediated side effects, discontinuation of study drug or addition of steroids often reverses the effect. However, in some instances, replacement hormones may be required (hypophysitis and thyroid dysfunction).

Patients treated with pembrolizumab who then go on to allogeneic stem cell transplant (a procedure in which a person receives blood-forming stem cells from a donor), should inform their transplant physicians that they have received pembrolizumab in the past.

In patients with any hematologic malignancy (cancers of the blood like Hodgkin lymphoma,

multiple myeloma): there is a potential for an increased risk of severe complications following allogeneic stem cell transplant in patients who previously received pembrolizumab.

Reports clotting of blood within the liver and severe graft versus host disease (which can include skin, liver and gastrointestinal symptoms), including
death, have been received for patients who received allogeneic stem cell transplant after pembrolizumab therapy.

Additional serious side effects seen in less than 1 out of 100 patients treated with pembrolizumab include the following:
Dizziness or fainting (low blood pressure), flushing, rash, fever, shortness of breath or sick to your stomach at the time of receiving your infusion (IV) or just after, or pain at the site of infusion.

In addition to the above, the following side effect(s) have been seen in patients on pembrolizumab, but are still being evaluated to determine if they are related to the drug:
A condition where you will feel weakness and fatigue of your hip and thigh muscles and an aching back caused by your body's immune system attacking your healthy cells and tissues.

Pembrolizumab treatment has rarely been associated with development of sarcoidosis. Sarcoidosis is an inflammatory disease that affects multiple organs in the body.

Some side effects of pembrolizumab may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects.

Monitoring/Precautions/Safeguards for toxicity:

1. We will closely monitor your blood counts and treat any abnormality according to the standard guidelines.
2. We will have well planned visit schedules for physical exam and assessment of any toxicity.
3. Patients who are on any medications or herbal supplements that expose them to more toxicity or decreased effectiveness of therapy, will be counseled to either replace this medicine or not take part in the trial.

Risks of combining pembrolizumab with cisplatin and radiation:

We are not sure of all the risks of combining pembrolizumab with cisplatin and radiation. This is why we are performing this study. Combining these treatments could result in previously unknown side effects.
<u>For patients undergoing laryngectomy after having been exposed to chemotherapy in combination with radiation, there appears to be a significantly worse survival outcome.</u>

Blood Draws
There may be risks of drawing blood (venipuncture). Risks of having your blood drawn include faintness, inflammation of the vein, pain, bruising, bleeding at the site of the puncture and, rarely, infection.

CAT or CT scan
A CAT scan (or CT scan)- During this study you will receive a CT scan that involves X-ray. This means that you will be exposed to radiation. Radiation from X-ray procedures may result in a greater incidence of cancer in the future.

The CT scans that you will undergo are part of your standard medical care. You should discuss the risks of a CT scan, as well as the risks of not having a CT scan with your doctor.

You should ask the CT technologist if every effort will be made to minimize radiation exposure during your X-ray tests, including proper use of the X-ray machines and the use of high quality imaging instruments. If an adequate answer is not obtained from the technologist, you should insist on talking to the radiologist prior to the scan.

PET Scan
Positron Emission Tomography (PET) can help doctors determine the source of cancer. This is possible because many cancer cells begin to grow at a much faster rate than normal cells and use up more sugars (like glucose) than normal cells. In order to prepare for the PET scan, you should wear comfortable, loose-fitting clothing, and not eat for four hours before the scan. You will be encouraged to drink plenty of water. Your doctor will instruct you regarding the use of medications before the test.
To begin the procedure, a small amount of radioactive glucose (or similar tracer) is injected into your bloodstream. You will wait about an hour while the tracer travels through your body emitting signals and eventually collects in the organs targeted for examination. If an area in an organ is cancerous, the signals will be stronger than in the surrounding tissue because more of the glucose is being used. You will be asked to lie on a table that passes slowly through the scanner. The scanner resembles a CT scanner, but has a much larger opening. A scanner records signals from your body and transforms them into pictures of chemistry and function on a computer screen. It typically takes 30-45 minutes to complete the scan.

WHAT ARE THE REPRODUCTION RISKS?

Because the drug(s) in this research study can affect an unborn baby, and pembrolizumab may increase these risks, you must not become pregnant or cause a pregnancy while in this research study.

If you are able to become pregnant or cause a pregnancy, you must use two forms of birth control. The two birth control methods can be either two barrier methods or a barrier method plus a hormonal method to prevent pregnancy. Subjects should start using birth

control from study Visit 1 throughout the study period up to 120 days after the last dose of study therapy.
You must use an adequate method of birth control during this study. You must discuss birth control options with your study doctor.

You must notify the study doctor and your treating physician immediately if you become pregnant or suspect that you have caused a pregnancy while on the study or within 120 of completing the study.
If you or your partner become pregnant, the treatment used in this research study might involve unknown risks to the embryo or fetus. The study doctor will wish to follow the outcome of any pregnancy and condition of any newborn.

You should not nurse your baby while on this research study.

ARE THERE BENEFITS TO TAKING PART IN THE RESEARCH STUDY?

If you agree to take part in this study, there may not be a direct medical benefit to you. We hope the information learned from this research study will also benefit other patients with advanced head and neck cancer in the future.

The information obtained from this study may benefit the study sponsor Vinita Takiar, MD, by providing information that will be helpful to future studies.

WHAT OTHER CHOICES FOR CARE ARE THERE?

Your other choices may include:

- Receiving standard chemotherapy without the addition of pembrolizumab.
- Getting treatment or care for your cancer without being in a study.
- Taking part in another study.
- Getting no treatment.

Talk to your study doctor about your choices before you decide if you will take part in this study.

WHAT IS THE CLINICAL TRIALS REGISTRY?

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

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.

AVAILABILITY OF INFORMATION

You will receive a copy of this signed and dated consent form.

You will be told about any new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

WHAT ARE YOUR COSTS TO BE IN THIS STUDY?

You will receive the study medication, pembrolizumab, and the study-related blood draws and biopsy at no cost.

You and/or your health plan/ insurance company will need to pay for some of the costs of treating your cancer in this study that are standard of care. Standard of care means that these procedures are part of regular cancer treatment and would be done even if you were not participating in a research study. This includes the standard chemotherapy with cisplatin, radiation, CT scans, biopsies and other procedures that are not considered study procedures. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?

You will not be paid for taking part in this study

WHAT COMPENSATION IS AVAILABLE IN CASE OF INJURY?

In the event that you become ill or injured from participating in this research study, emergency medical care will be provided to you. The University of Cincinnati will decide on a case by case basis whether to reimburse you for your out of pocket health care expenses.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

You may choose either to take part or not to take part in this research study. If you decide to take part, you may decide to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you.

The investigators will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

If you have questions about the study, you will have a chance to talk to one of the study staff or your regular doctor. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

Nothing in this consent form waives any legal rights you may have nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE AND CONFIDENTIAL?

Authorization to Use and Disclose Health Information

A federal regulation known as the Privacy Rule gives you certain rights concerning the privacy of your health information. Researchers covered by this regulation are required to get your authorization (permission) to use and disclose (share with others) any health information that could identify you. You should have received a Notice of Privacy Practices when you received health care services here. If not, let us know and a copy will be given to you.

If you sign this informed consent form, you are giving permission for the use and disclosure of your health information for purposes of this research study. You do not have to give this permission. Your health care outside of the study, payment for your health care, and your health care benefits will not be affected if you choose not to sign this form. However, if you do not sign this form, you will not be able to participate in the study.

Who Will Use and Disclose My Health Information?

The study doctor and research staff (the study team) may use your health information to conduct, review, and determine the results of the study. The study team may also use your information to prepare reports or publications about the study. However, your name will not appear in any report or publication without your permission.

What Health Information will be Used and Disclosed?

The study team will record your medical history, the treatment you receive, and the results of examinations and tests done during the study on study forms. The study team will send the completed study forms to the study sponsor. Representatives from the groups identified below may need to look at your medical records to make sure that the information on the study forms is correct or that the study was conducted properly. Your medical records may include other health information about you and may include documents that directly identify you. Reviews like that will take place at the study center or where the medical records are stored and can take place after the study is over.

Who Will Receive My Health Information?

Your study information or medical records (as described above) or both may be shared with the following people or groups:

There are organizations that may inspect your records. These organizations are required

to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- Researchers who are conducting this study at other study centers
- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- Staff of the UC Human Research Protection Program
- UC or UC Health employees that provide care to you.
- The Food and Drug Administration and the National Cancer Institute in the U.S., and similar ones if other countries are involved in the study.
- University of Cincinnati

Will My Information be Protected by the Privacy Rule After it is Disclosed to Others?
UC Health and the University of Cincinnati are required by the Privacy Rule to protect your health information. After your information is shared with others, such as the study sponsor, it may no longer be protected by the Privacy Rule. The people who receive this information could use it in ways not discussed in this form and could disclose it to others. The sponsor will use and disclose your information only for research or regulatory purposes or to prepare research publications. In addition to using it for this study, the sponsor may reanalyze the study data at a later date or combine your information with information from other studies for research purposes not directly related to this study. The goal of any such research would be to learn more about drugs or diseases or to help design better studies in the future. When using your information in these ways, the sponsor may share it with regulatory authorities, other researchers, its business partners, or companies it hires to provide research-related services.

What Happens if I Leave the Study Early?
If you stop participating in the study early for any reason, the study team will tell the sponsor why. If the study team asks you to come to any more study visits and you agree, the study team will send the sponsor information from those visits as well. All information collected about you may continue to be used and disclosed.

Will My Authorization Ever Expire?
This Authorization does not have an expiration date. The study team may need to correct or provide missing information about you even after your study participation is over and a review of your medical records may also take place after the study is over.

May I Take Back My Authorization?
You have the right to take back (revoke) your Authorization at any time by writing to the person in charge of this research study whose information is listed on the front of this form. If you revoke your Authorization, the study team will not collect any new health information about you. However, they can continue to use and disclose any already-collected information if that is necessary for the reliability of the study. The sponsor can also still keep and use any information that it has already received. If you revoke your Authorization, you can no longer continue to participate in the study.

May I Look At My Study Information?
You have a right to see and make copies of your medical records. However, to ensure the reliability of the study, you will need to wait to see your study records until the study is completed.

Your research information will be saved in your UC Health medical record. UC Health employees providing service or care to you will be able to see it.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

If you have non-urgent questions, concerns, complaints and/or suggestions about this research study or to report a research-related injury, please contact the researcher Vinita Takiar, MD at 513-584-7698. If you are concerned about a serious or urgent medical issue, you should first contact your doctor or call 911, depending on the situation.

Please call the University of Cincinnati Institutional Review Board at 513-558-5259 (Monday – Friday 8 am to 5 pm) if you:

- Think the research has hurt you.
- Have general questions about giving consent or your rights as a research participant in this research study.
- Have questions, concerns, complaints and/or suggestions about the research.
- Cannot reach the research team or you want to talk to someone else.

To report complaints or concerns to an independent agency in an anonymous and confidential manner, please call the Research Compliance Hotline at 1-800-889-1547.

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CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: A Phase I/ II Study of chemo radiation plus the Anti-PD-1 Antibody, Pembrolizumab (MK-3475) for Locally Advanced Laryngeal Squamous Cell Carcinoma

UC IRB Study #: 2015-8190 **Sponsor Name:** Investigator-Initiated

Investigator Information:

Vinita Takiar, MD	513-584-7698	513-584-7661
Principal Investigator Name	Telephone Number	24 hr Emergency Contact

Subject Name: _____ Date of Birth: _____/_____/____

I have read or someone has read to me, this Informed Consent Document which describes the purpose and nature of this research. I have had time to review this information and have been encouraged to ask questions. If I do not participate or if I discontinue my participation, I will not lose any benefits or any legal rights. My participation in this research is completely voluntary. I have received (or will receive) a copy of this signed and dated form for my records and future reference. I have been given the information about the use and disclosure of my health information for this research study.

Participant Date

PERSON OBTAINING CONSENT
I have read this form to the participant and/or the participant has read this form. An explanation of the research was given and questions from the participant were solicited and answered to the participant's satisfaction. In my judgment, the participant has demonstrated comprehension of the information.

Signature and Title of Person Obtaining Consent and Identification of Role in the Study Date