Informed Consent Form

Winship4234-17: A phase II trial of pembrolizumab and cabozantinib in patients with RM SCCHN who have failed platinum based therapy

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EMORY UNIVERSITY | Institutional Review Board
Research Administration

EMORY | WINSHIP CANCER INSTITUTE

A Cancer Center Designated by the National Cancer Institute

You Are Being Asked to Be in a Research Study

What Is a Research Study?

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

Do I Have to Do This?

No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

What Is This Document?

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

This form is also a HIPAA Authorization document. It will describe how your health information will be used and by whom.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

What Should I Do Next?

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. Take time to consider this, and talk about it with your family and friends.

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: A phase II trial of pembrolizumab and cabozantinib in patients with RM SCCHN

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Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

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.

What is the purpose of this study?

The purpose of this study is to test whether the combination of two anti-cancer drugs, pembrolizumab and cabozantinib, will improve the chances of your head and neck cancer responding to treatment. We will also be examining the type of side effects that may result from the combination of these two anticancer drugs.

Pembrolizumab is approved as a single agent for the first-line treatment of patients with metastatic or unresectable recurrent SCCHN whose tumors express PD-L1 CPS ≥ 1% ; in addition, Pembrolizumab in combination with platinum and fluorouracil is approved for the first-line treatment of patients with metastatic or unresectable, recurrent SCCHN regardless of PD-L1 CPS status Cabozantinib is an anticancer drug that is currently not approved for the treatment of your type of head and neck cancer (squamous cell carcinoma) but has been approved for the treatment of other

types of cancer such as thyroid cancer and kidney cancer; we believe that the combination of pembrolizumab and cabozantinib will improve the chances of your cancer responding to treatment more so than pembrolizumab alone.

This combination has not been given to patients with your type of cancer, but similar combinations with a drug called nivolumab and cabozantinib has been given to patients with kidney cancer. The study you are being offered will be also looking at whether there are any particular side effects that can happen with the combination of cabozantinib and pembrolizumab in patients like yourself who have squamous cell cancer of the head and neck. Pembrolizumab and nivolumab, another anti-PD-1 antibody, are FDA-approved as single agents for the treatment of patients with SCCHN in the recurrent setting. The addition of cabozantinib to pembrolizumab may help improve the outcome of patients but may also lead to increased toxicity and the potential for dose delay of pembrolizumab which may negate the additional benefit compared to pembrolizumab alone.

What will I be asked to do?

Screening Period

This period may include more than one study visit for various procedures. At the Screening Visit you will be asked to read and sign this informed consent before any study related procedures that are not standard of care are performed. It is your right as a subject to have the study fully explained to you and you can ask that your study doctor explain or go over any parts of this informed consent that you do not understand.

The following tests and procedures will be performed by the study staff to determine if you qualify to participate in this study. Unless otherwise stated, these exams, tests, or procedures are part of regular cancer care and may be done even if you do not join the study.

1- Review of your medical history.
2- Review of medications you are currently taking and have taken in the past including herbal medications.
3- A physical examination including measurement of your height, weight and vital signs (temperature, blood pressure, and heart rate).
4- You will be asked about the symptoms you are having from your disease, this procedure is also called determination of your performance status.
5- Collection of your blood for laboratory tests which measure your blood chemistry, including kidney and liver function, count your red and white blood cells and platelets, and check for PT/PTT/INR. Your tumor may be tested for human papillomavirus (HPV) if not known depending on the location of your original tumor.
6- A blood test for research purposes will also be obtained before treatment starts. Blood collection for research will also be obtained at screening, 9 weeks, at 6 months, and end of treatment (or at the time of progression whichever is sooner). Therefore a total of 4 blood draws will need to be obtained for research purposes.
7- If you have had a tumor biopsy/cancer surgery in the past, your study doctor will request the original samples from the medical facility where it was done. In order to participate in this study, you must provide your permission to obtain these original samples and allow your study doctor to send them to a laboratory for research testing. If no biopsy was performed after your cancer came back you will asked to have a biopsy performed of your tumor or one of its

metastatic lymph nodes; if needed, this biopsy would be performed for research purposes only. An optional end of treatment tumor biopsy (or at the time of progression) may be requested from you; this is an optional biopsy at Moffitt site only.

8- A computed tomography (CT) scan or PET/CT scan or MRI of head and neck, brain, chest, and all other known areas of disease will be done. These are special procedures which use X-rays (in the case of CT) or magnetic fields (in the case of MRI) to create pictures of the inside of your body. These pictures will allow your doctor to monitor your disease before, during, and after you receive pembrolizumab and cabozantinib.

9- A urine or blood pregnancy test for women of childbearing potential must be performed before the first dose of study medication is given. Results of the pregnancy test must be negative for you to participate in this study.

About 34 subjects are expected to participate in this study from different participating institutions. Emory plans to enroll close to 26 subjects. The first 6 to 9 patients will receive the full dose of pembrolizumab and cabozantinib and will be observed very closely for any significant side effects. The next 28 patients will receive either the full dose or a reduced dose of cabozantinib based on information your physicians will have from treatment of the first 6 to 9 patients.

Even though you may meet all the criteria for participation, it is possible that you will not be enrolled in this study. If, based on the results of the screening visit tests and procedures, you qualify to participate in the study, you will return to the study doctor's office for the Baseline Visit.

Treatment:
If you qualify to participate in the study based on the results of the screening visit tests and procedures, you will return to the study doctor's office/clinic. You will then begin therapy.

Pembrolizumab will be given as an intravenous (IV) infusion that takes approximately one hour (60 minutes). Intravenous infusion means that the drug is administered as a liquid substance directly into a vein. A pump will be used for the intravenous infusions to ensure the correct amount of medicine is given over the proper amount of time. Pembrolizumab will be given every 3 weeks starting the first day of treatment.

Cabozantinib will be given in a pill form on a daily basis during the treatment and will not be interrupted unless there are observed side effects that your physician believes are related to either pembrolizumab or cabozantinib. Cabozantinib must be taken on an empty stomach. You will be instructed not to eat for at least 2 hours before and at least 1 hour after taking cabozantinib. Cabozantinib tablets should be swallowed whole with at least 8 ounces of water. The tablets should not be crushed. Grapefruit, grapefruit juice, Seville oranges and their products should be avoided by subjects taking cabozantinib.

How will my medicine be provided?
The medicine that you will take will be dispensed by the pharmacy and delivered to the principal investigator or study team member. The principal investigator or health care providers on his/her research team will provide the medicine to you. If you have questions about the medicine, you should ask the principal investigator or study nurse. You may also call the pharmacy if you have questions about the medicine. The number for the pharmacy is included on your medicine package.

If you experience any changes in your body or develop any new or worsening side effects during or after the infusion you should inform the study doctor or nurse immediately.

During the Treatment Period, you will be asked questions about your condition including:

1- How your cancer is affecting your daily activities.
2- What medications you have taken or are currently taking including herbal supplements and over-the-counter medicines.
3- What side effects you have experienced. During your clinic visits, you should report the development of any new or worsening medical problems (since your last visit) to the study doctor or other study personnel taking care of you.

The following procedures/samples will be performed and/or collected at 1 or more visits:

1- A brief physical examination, including body weight and examination of performance status every 3 weeks (on the days you receive pembrolizumab) and after completing treatment until you recover from any side effects related to treatment. Follow up after this will be at the discretion of your treating doctor and may be done by phone calls if for any reason you cannot come in to clinic.
2- Vital sign measurements (blood pressure, heart rate, weight) will be assessed on the day of infusion. If you develop a reaction during the infusion, you will continue to have your vital signs measured until the study doctor determines it is no longer necessary.
3- Blood samples will be drawn to assess 1 or more of the following:
   - Blood chemistry, including kidney and liver function, red and white blood cells and platelets count, and coagulation tests (PT/PTT/INR), These tests will take place every 3 weeks (on the days you receive pembrolizumab)
   - Collection of blood (approximately 20ml before the start of treatment and 9 weeks into the treatment, at 6 months, and end of treatment (or at the time of progression whichever is sooner). for biomarker tests (substances in your blood such as cells, proteins, DNA, RNA, or other markers). Measuring biomarkers in the blood could help predict whether or not someone is likely to benefit from the drug combination in future. These biomarker studies are for research purposes only.
4- A CT scan, MRI, or PET/CT of your neck as well as any other areas of disease or potential disease spread will be obtained every 9 week while you are on treatment, and every 3 months for the first year after you finish the treatment and then at the discretion of your treating physician or at any time if your disease has worsened or you stop receiving the study treatment (whichever occurs later).

You may be discontinued from receiving study treatment based on your disease assessments or if you are having side effects that make you unable to tolerate study therapy. Based on discussions between you and your study doctor, you may discontinue for other reasons including your decision to stop being treated.
If you continue to benefit from the treatment at 2 years after starting the program, you will be given the option of either stopping the treatment or continuing with the combination using the commercial source of cabozantinib provided by the pharmaceutical company. This decision will have to be made in consultation with your physician.

Who owns my study information and samples?
If you join this study, you will be donating your samples and study information. You will not receive any compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already collected may be still be used for this study.

What are the possible risks and discomforts?
There may be side effects from the study drug or procedures that are not known at this time.

Pembrolizumab

What is known about this study drug?

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. These side effects may be serious (i.e., causing hospitalization or be life-threatening), may result in death, and/or may occur after you stop taking pembrolizumab. These side effects can affect more than one of your normal organs and tissues at the same time.

What side effects could the study drug(s) cause?

VERY COMMON

Out of 100 people who receive pembrolizumab, 20 or more people may have the following:
- Rash
- Nausea
- Fatigue
- Cough

COMMON

Out of 100 people who receive pembrolizumab, at least 5 but less than 20 people may have the following:
- Joint pain
- Cough
- Anemia
- Itching of the skin
- Fever
- Back pain
- Pain in your belly
- Loose or watery stools
- Loss of skin color

Not enough thyroid hormone, so you may feel tired, gain weight, feel cold, or have infrequent or hard stools (hypothyroidism)

Low levels of salt in the blood that may cause you to feel tired, feel confused, have a headache, have muscle cramps, and/or feel sick to your stomach (hyponatremia)

UNCOMMON

Out of 100 people who receive 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 (pneumonitis)
- Too much thyroid hormone, so you may feel anxious, feel angry, have trouble sleeping, feel weak, tremble, sweat, feel tired, have loose and watery stools (hyperthyroidism)
- Infusion reaction, where you may feel dizzy or faint, feel flushed, get a rash, have a fever, feel short of breath, experience a decrease in your blood pressure at the time of receiving your infusion (IV) or just after, or have pain at the site of infusion
- Inflammation of the bowels/gut, which may cause severe pain in your belly with loose or watery stools, and black, tarry, sticky stools or stools with blood or mucus (colitis)
- Inflammation of the skin so you may have peeling of the skin, itchiness, and/or 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 (Severe skin reactions, including Stevens-Johnson syndrome or toxic epidermal necrolysis)

RARE

Out of 100 people who receive pembrolizumab, less than 1 person may have the following:

- Inflammation of the nerves that may cause pain, weakness, or tingling in your hands and feet, and may spread to your legs, arms, and upper body, leading to severe muscle weakness and possible temporary paralysis (Guillain-Barré syndrome)
- Inflammation of the muscles, so you may feel weak or have pain in your muscles (myositis)
- 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 have vomiting that gets worse when you eat (pancreatitis)
- Inflammation of the eye, so you may have eye redness, blurred vision, sensitivity to light, eye pain, see floaters, or have headaches (uveitis)
- Inflammation of the liver that may make you feel sick to your stomach and vomit, feel like not eating, feel tired, have a mild fever, a pain in the right side of your belly, yellow eyes and skin, and dark urine (hepatitis)
- Inflammation of the pituitary gland (a gland in the head), which may cause you to feel sick to your stomach or have headaches, 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) that 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.

- 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 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.
- 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, 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
- Inflammation of the spinal cord with pain, numbness, tingling, or weakness in the arms or legs, bladder or bowel problems including needing to urinate more frequently, urinary incontinence, difficulty urinating, and constipation
- Inflammation of the blood vessels
- Low levels of parathyroid hormone (a hormone made by 4 tiny glands in your neck) which may result in low blood calcium and cause muscle cramps or spasms; fatigue or weaknesses; numbness, tingling or burning in your fingertips, toes or lips (hypoparathyroidism)

Additionally, since pembrolizumab was approved in September 2014, the following side effects have been reported by people receiving pembrolizumab. These side effects were voluntarily reported from a group of people of unknown size. It is not possible to estimate the frequency of this side effect:

- Inflammation of the joints which may include join pain, stiffness and/or swelling (arthritis)
- Severe responses of the immune system that cause the body to attack its own blood cells, spleen, liver, lymph nodes, skin and brain. This may include fever, rash, inflammation of the liver, yellowing of the skin, an enlarged liver and spleen, low blood counts, and enlarged lymph nodes. The nervous system may also be affected and cause confusion, seizures, and even coma.
- Changes in eyesight, eye pain, whitish patches on the skin and hearing loss (Vogt-Koyanagi-Harada syndrome)
- Inflammation and scarring of the bile ducts (tubes that carry digestive fluid that is made in the liver). This can cause symptoms similar to those seen with inflammation of the liver (hepatitis) such as pain in right side of your belly, yellow eyes and skin, feeling tired, and itching (sclerosing cholangitis).
- Inflammation or swelling of the nerve fibers of the eye which send visual information from your eye to your brain. This health condition often has a sudden onset of vision loss, loss of color vision, pain when moving your eyes, and/or loss of peripheral vision. It may affect one or both eyes at the same time (optic neuritis).

Cabozantinib

Very Common Side Effects that Occurred in ≥ 10% of Cancer Patients (≥ 1 in 10) Treated with Cabozantinib

- Abdominal pain [eg. abdominal pain, 9.3%; abdominal pain upper, 4.1%]
- Alteration of thyroid function tests [hypothyroidism, 11.3%, blood thyroid stimulating hormone increased, 4.1%]
- Blisters, rash, or pain in hands or feet [palmar-plantar erythrodysaesthesia syndrome, 36.8%; erythema, 2.6%]
- Changes in blood tests used to monitor the liver, which may indicate liver damage [AST increased, 16.1%; ALT increased, 14.6%; GGT increased, 3.1%; hepatic enzyme increased, 0.7%; transaminases increased 1.5%; liver function test increased, 0.4%]
- Change in voice [dysphonia, 19.2%; vocal cord paralysis, 0.1%]
- Changes to the way things taste [dysgeusia, 11.2%; ageusia, 1.4%; hypogeusia, 0.4%]
- Constipation [constipation, 12.2%]
- Diarrhea [diarrhea, 52.3%]
- Fatigue [fatigue, 48.6%]
- Hair color changes or hair loss [hair color changes, 9.1%; alopecia, 6.0%]
- High blood pressure [hypertension, 25.0%]
- Inflammation of mucus membranes [mucosal inflammation, 17.0%; anal inflammation, 0.7%; genital tract
- Inflammation, 0.2%; gingival swelling, 0.2%; laryngeal inflammation, 0.2%; nasal inflammation, 0.3%; oral mucosal erythema, 0.1%; pharyngeal inflammation, 0.3%; vulvovaginal inflammation, 0.1%]
- Loss of appetite [decreased appetite, 41.6%]
- Mouth and throat sores or swelling [stomatitis, 17.4%; mouth ulceration, 1.5%; cheilitis, 0.5%; glossitis, 1.0%; tongue blistering, 0.1%]
- Nausea [nausea, 38.4%]
- Rash [rash, 11.9%; rash pruritic, 0.3%; rash macular, 0.3%; dermatitis, 0.6%; dermatitis bullous, 0.2%; exfoliative rash, 0.3%; genital rash, 0.2%; rash erythematous, 0.6%; rash follicular, 0.1%; rash maculo papular, 1.1%; rash papular, 0.5%; rash pustular, 0.2%]
- Vomiting [vomiting, 23.0%]
- Weakness [asthenia, 17.6%]
- Weight loss [weight decreased, 25.3%]

Common Side Effects That Occurred ≥ 1% but < 10% of Cancer Patients (≥ 1 in 100, but < 1 in 10) Treated with Cabozantinib

- Abnormal thickening of the outer layer of the skin [hyperkeratosis, 2.1%]
- Change in the feeling of touch [paraesthesia, 2.2%; dysaesthesia, 0.4%; hyperaesthesia, 0.8%, hypoaesthesia,1.0%]
- Cough [cough, 3.0%]
- Bleeding, including bleeding from stomach or intestines which may look like coffee grounds or black sticky bowel movements and bleeding within the brain [haemorrhage, 0.2%; gastrointestinal haemorrhage, 0.2%; upper gastrointestinal haemorrhage, 0.2%, ulcer haemorrhage, 0.03%; intracranial tumour haemorrhage, 0.1%; tumour haemorrhage, 0.03%; cerebral haemorrhage, 0.1%; haematoma, 0.3%; cerebral haematoma, 0.1%; haemoptysis, 0.6%; haematochezia, 0.3%; haematemesis, 0.2%; haematuria, 0.8%; respiratory tract

haemorrhage, 0.1%; arterial haemorrhage, not related SAE rate 0.03%; gastric haemorrhage, 0.03%; Mallory-Weiss syndrome, 0.1%; oesophageal haemorrhage, 0.03%; gastrointestinal ulcer haemorrhage, 0.03%; rectal haemorrhage, 0.6%; muscle haemorrhage, not related SAE rate 0.03%; gingival bleeding, 1.2%; epistaxis, 4.1%; anal haemorrhage, 0.2%; bronchial haemorrhage, 0.03%; conjunctival haemorrhage, 0.1%; duodenal ulcer haemorrhage, 0.1%; ear haemorrhage, 0.03%; ecchymosis, 0.03%; haemorrhage intracranial, 0.1%; haemorrhage urinary tract, 0.03%; haemorrhoidal haemorrhage, 0.2%; intestinal haemorrhage, 0.03%; lower gastrointestinal haemorrhage, 0.03%; melaena, 0.1%; metrorrhagia, 0.1%; peritoneal haemorrhage, 0.03%; post procedural haemorrhage, 0.03%; pulmonary haemorrhage, 0.03%; skin haemorrhage, 0.1%; splinter haemorrhages, 0.2%; subdural haematoma, 0.03%; tongue haemorrhage, 0.1%; tracheal haemorrhage, 0.03%; vaginal haemorrhage, 0.2%]

- Blood clot in a large vein, usually in the leg [eg, deep vein thrombosis, 1.6%; portal vein thrombosis, 0.3%; pelvic venous thrombosis, 0.1%; venous thrombosis limb, 0.1%]
- Blood clot that travels from a vein to the lung [eg, pulmonary embolism, 3.3%; embolism, 0.1%]
- Confusion and disorientation [eg, confusional state, 1.3%; mental status changes, 0.2%; delirium, 0.2%]
- Decreased amounts of red blood cells (anemia), which may cause feelings of tiredness or shortness of breath [anaemia, 7.6%; haemoglobin decreased, 0.7%]
- Decreased amounts of calcium or sodium in the blood [hypocalcaemia, 5.0%; blood calcium decreased, 0.5%; hyponatraemia, 2.5%; blood sodium decreased, 0.2%]Decreased or increased amounts of potassium in the blood [hypokalaemia, 5.3%; blood potassium decreased, 0.5%; hyperkalaemia, 0.8%; blood potassium increased, 0.1%]
- Decreased amounts of magnesium or phosphorus in the blood [hypomagnesaemia, 6.9%; blood magnesium decreased, 0.8%; hypophosphataemia, 5.1%; blood phosphorus decreased, 0.7%]
- Decreased level of albumin in the blood [hypoalbuminaemia, 2.3%; blood albumin decreased, 0.6%]
- Decreased platelet counts, which increases the risk of bleeding or make bleeding more difficult to stop [thrombocytopenia, 6.8%; platelet count decreased, 3.9%]
- Decreased white blood cell counts, which may increase chances of infection [neutropenia, 5.4%; leukopenia, 4.1%; lymphocyte count decreased, 0.8%; lymphopenia, 2.0%; neutrophil count decreased, 2.4%; white blood cell count decreased, 2.3%]
- Dermatitis acneiform, a type of acne [eg, acne, 1.0%, dermatitis acneiform, 2.0%]
- Dehydration [dehydration, 4.7%]
- Difficulty swallowing [dysphagia, 3.7%]
- Dizziness [dizziness, 6.1%]
- Dry mouth [dry mouth, 8.6%]
- Dry skin [dry skin, 8.3%]
- Fever [pyrexia, 1.9%]
- Fungal infections including mouth, lung, and other locations [eg, aspergilloma, 0.1%; oral candidiasis, 1.1%]
- Hemorrhoids [haemorrhoids, 1.4%] and bleeding hemorrhoids [haemorrhoidal haemorrhage, 0.2%]
- Headache [headache, 5.9%]
- Increased amounts of pancreas enzymes in the blood, which may indicate damage to the pancreas [lipase increased, 4.7%; amylase increased, 3.4%; pancreatitis 0.6%, pancreatitis acute, 0.2%]

- Increased levels of bilirubin in the blood, which may indicate complications with the liver [blood bilirubin increased, 2.9%; hyperbilirubinaemia, 1.0%]
- Increased levels of creatinine in the blood, which may indicate complications with the kidneys [blood creatinine increased, 1.5%]
- Mouth or throat pain [oral pain, 6.7%; oropharyngeal pain, 4.6%; glossodynia, 3.3%; oral discomfort, 0.6%]
- Muscle spasm [muscle spasm, 5.4%]
- Muscle weakness [muscular weakness, 1.9%]
- Pain in a joint or muscle [arthralgia, 3.1%; musculoskeletal chest pain, 0.6%]
- Pain in extremities [pain in extremity, 6.4%]
- Protein in the urine, which may indicate kidney damage [proteinuria, 5.9%]
- Shortness of breath [dyspnoea, 6.4%]
- Stomach acid coming up from the stomach into the esophagus [eg, gastroesophageal reflux disease, 4.1%; oesophagitis, 0.6%]
- Swelling of the limb(s) [oedema peripheral, 3.7%]
- Ulcer [eg, anal ulcer, 0.2%; oesophageal ulcer, 0.1%; skin ulcer, 1.5%]
- Upset stomach or indigestion [dyspepsia, 8.6%]

Uncommon Side Effects That Occurred ≥ 0.1% but < 1% of Cancer Patients (≥ 1 in 1000, but < 1 in 100)

- Abnormal electrical activity in the heart that could cause a potentially serious change in heart rhythm [eg, ventricular arrhythmia, 0.03%; electrocardiogram QT prolonged, 0.8%; atrioventricular block, 0.1%]
- Abnormal opening between two organs or from an organ to the outside of the body [acquired tracheo oesophageal fistula, 0.1%; gastrointestinal fistula, 0.03%; oesophageal fistula, 0.03%; anal fistula, 0.4%; enterocutaneous fistula, 0.03%; enterovesical fistula, 0.1%; gastric fistula, not related SAE rate 0.03%; tracheal fistula, 0.1%; fistula, 0.1%]
- Abscesses (infected cavities filled with pus) [abdominal abscess, 0.03%; gingival abscess, 0.1%; lung abscess, 0.1%; colonic abscess, 0.1%; perirectal abscess, 0.2%; rectal abscess, 0.2%; anal abscess, 0.4%; pharyngeal abscess, 0.03%; periumbilical abscess, 0.03%; tooth abscess, 0.4%]
- Blood clot in an artery [peripheral artery thrombosis, 0.03%; intestinal ischaemia, 0.1%; carotid artery thrombosis, 0.03%; cerebral ischaemia, 0.1%; transient ischaemic attack, 0.2%]
- Chest discomfort originating from the heart [angina pectoris, 0.1%]
- Clouding of the lens in the eye that affects vision [cataract, 0.1%]
- Damage to skeletal muscle tissue [rhabdomyolysis, 0.1%]
- Decreased brain function or decreased alertness and ability to think [eg, encephalopathy, 0.2%; hepatic encephalopathy, 0.3%]
- Decrease in all blood counts (red blood cells, white blood cells and platelets) [pancytopenia, 0.2%]
- Destruction of bone tissue, in particular, bone in the jaw [eg, osteonecrosis of jaw, 0.5%; osteonecrosis, 0.03%]
- Feelings of unease or fear [anxiety, 0.7%]
- Gallstones [cholelithiasis, 0.1%]
- Heart attack [eg, acute myocardial infarction, 0.2%; myocardial infarction, 0.03%; myocardial ischaemia, not related SAE rate, 0.03%]
- Heart failure [cardiac failure, 0.2%]

- Holes in the stomach or intestines [diverticular perforation, 0.1%; gastric perforation, 0.1%; gastrointestinal perforation, 0.1%; intestinal perforation, 0.1%; small intestinal perforation, 0.1%; large intestine perforation, 0.3%; appendicitis perforated, 0.1%; rectal perforation, not related SAE rate 0.03%; pneumoperitoneum, not related SAE rate 0.1%]
- Infections [eg, osteomyelitis, 0.1%; wound infection, 0.03%; postoperative wound infection, 0.03%; sepsis, 0.2%; septic shock, 0.03%]
- Inflammation of the intestine, appendix, gall bladder or thin tissue lining the inner wall of the abdomen and most of the abdominal organs [eg, appendicitis, 0.1%; colitis, 0.2 %; colitis ischaemic, 0.1%; cholecystitis, 0.1%; enterocolitis, 0.03%; peritonitis, 0.1%; proctitis, 0.3%]
- Reduced kidney function [eg, renal failure, 0.3%; acute kidney injury, 0.6%; prerenal failure, 0.03%; nephrotic syndrome, 0.1%; nephropathy, 0.1%]
- Liver failure [hepatic failure, 0.2%]
- Loss of consciousness, fainting episode [eg, loss of consciousness, 0.2%; syncope, 0.4%]
- Pneumonia and inflammation of the lungs [pneumonia, 0.9%; pneumonia aspiration, 0.1%; pneumonitis, 0.1%]
- Rapid heart rhythm [eg, supraventricular tachycardia, 0.1%; atrial fibrillation, 0.3%]
- Re-opening of wounds after surgery [eg, wound dehiscence, 0.3%; postoperative wound complication, 0.03%; impaired healing, 0.6%]
- Respiratory failure [respiratory failure, 0.1%]
- Seizure [seizure, 0.2%]
- Stroke / mini-stroke [eg, cerebral infarction, not related SAE rate 0.1%; CVA, 0.1%; TIA, 0.2%; cerebral ischaemia, 0.1%; ischaemic stroke, 0.1%]
- Tear or inflammation in skin that lines the anus [anal fissure, 0.3%; anal inflammation, 0.7%]
- Uncoordinated movements [ataxia, 0.3%]
- Anemia
- Thrombocytopenia
- Hypothyroidism
- Anal fistula
- Gastrointestinal bleeding
- Pancreatitis

Rare but Medically important Side Effects not listed above that Occurred ≥ 0.01% but < 0.1% of Cancer Patients (≥ 10000, but < 1 in 1000) Treated with Cabozantinib

- Air in the chest between lungs and chest wall [pneumothorax, 0.1%; pneumomediastinum, 0.03%]
- Allergic reaction [hypersensitivity, 0.1%]
- Anemia caused by destruction of red blood cells [haemolytic uraemic syndrome, 0.03%]
- Blocked intestines [eg, intestinal obstruction, 0.03%; gastrointestinal obstruction, 0.03%]
- Brain dysfunction caused by brain swelling [eg, posterior reversible encephalopathy syndrome (PRES), 0.03%; leukoencephalopathy, 0.03%]
- Cancer of the mouth or skin [eg, squamous cell carcinoma of the oral cavity, 0.03%; squamous cell carcinoma, 0.03%]
- Damage to the outermost surface of the eye [corneal epithelium defect, 0.03%]
- Inflammation and blockage of channels that carry bile from the liver [hepatitis cholestatic, 0.03%; cholangitis, 0.03%]
- Severe swelling of the mouth, lips, tongue, eyes and throat, or difficulty swallowing or breathing [angioedema, 0.03%]

- Temporary paralysis of the intestines [ileus, 0.03%]
- Throat swelling [pharyngeal oedema, 0.03%]
- Very high blood pressure that comes on suddenly and quickly and which can lead to serious injury to the heart and brain [hypertensive crisis, 0.03%; malignant hypertension, 0.03%]

Reproductive Risks and Side Effects:

If you are a woman: to protect against possible side effects of the study drug, women who are pregnant or nursing a child may not take part in this study. If you become pregnant, there may be risks to you, the embryo, or fetus. These risks are not yet known. If you are a woman of childbearing ability, you and the study doctor must agree on a method of birth control to use throughout the study and for 4 months after the last dose, even if oral contraceptives are also used. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. Pregnant women will be taken out of the study.

If you are a man: the effect of the study drug on sperm is not known. To protect against possible side effects, if you are a man you should not get a sexual partner pregnant while taking the study drug and for 90 days after the last dose. You and the study doctor should agree on a method of birth control to use throughout the study.

If you will be taking the study drug home, keep it out of the reach of children or anyone else who may not be able to read or understand the label. Do not let anyone else take the study drug besides you.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Risks from Other Procedures:
Venipuncture/Intravenous Needle Insertion: The collection of a blood sample may cause some discomfort. Obtaining blood may sometimes cause pain/discomfort at the site where the blood is drawn, bruising, bleeding, occasional lightheadedness, and, rarely, infection or fainting.

MRI: MRI exams use powerful magnets to create images of the body. In addition to the possible reactions to contrast materials, you may feel claustrophobic while in the magnet, and will hear loud beeping or hammering noises. If you have tattoos or any metal items in your body such as implants, pacemakers, clips or shrapnel, we will do special screening to make sure your MRI scan is done safely.

Contrast Agents: Your x-ray, CT or MRI procedure may require the use of a contrast agent, which is a substance that helps the radiologist interpret the images. The contrast agent will be injected by either a hand-held needle or a machine that does the injection. Most contrast agents stay in your body for only a few minutes, but some of them can remain for a few hours or days without any harm to you or anyone near you. Contrast agents are generally quite safe, but any injection involves some risks. The injection could harm a nerve, artery or vein, or cause infection. The contrast agent could affect kidney function or cause an allergic reaction, though these outcomes are rare. The contrast agent could also leak from your veins a little, causing swelling and discomfort, which is typically treated with ice packs.

PET: For your PET-CT scan, a small amount of radioactive material will be injected by either a hand-held needle or a machine. Such injections are generally quite safe, but any injection involves some risks. The injection could harm a nerve, artery or vein, or cause infection. The radioactive material could also leak from your veins a little, causing swelling and discomfort. After injection and a waiting period for the drug to circulate within your body, you will be asked to lie very still for several minutes while the scan takes place.

Biopsy: You may experience pain from this procedure that could also include bruising, soreness or scarring at the biopsy site. Rarely, a patient may experience infection and/or internal bleeding and depending on the location of the biopsy, 'punctured lung' and/or 'collapsed lung' (due to an abnormal collection of air or gas in the space that separates the lung from the chest). The biopsy procedure is usually performed while the patient is under local anesthesia (for example lidocaine), meaning the tumor site is numbed. Side effects from the local anesthesia are rare but may include convulsions or seizures, breathing problems, chest pain, rapid heart rate, irregular heartbeat, dizziness, bluish lips and fingernails, drowsiness, headache, itching, nausea and/or vomiting, raised red swellings on the skin, lips, tongue, or in the throat, restlessness, unusual tiredness or weakness, back pain, difficulty in opening the mouth, inability to hold bowel movement and/or urine, loss of sexual function, temporary paralysis (loss of function) of legs, persistent or prolonged numbness or tingling ("pins and needles" sensations) of lips and mouth, and shivering. Imaging equipment may be used to guide the needle to the desired site. This may involve ultrasound or x-ray. If x-ray is used, a patient is will be exposed to a small dose of radiation. In addition, a patient may be injected with a contrast dye (for example iodine). This may cause some side effects including hives, itching, lightheadedness, nausea and a metallic taste in the mouth. Rarely, the iodine may result in a severe allergic reaction, including shock, very low blood pressure and cardiac arrest.

ECG: You will also have an ECG which is a painless test that looks at the electrical activity of your heart by putting small sticky patches on your chest, arms and legs. These patches have thin wires that connect to a machine which will read and print a report. The test takes about 5-10 minutes. Some areas, where the patches will be placed, may need to be shaved. After the test, there may be a small amount of irritation where the patches were attached.

Radiation Risks

You will be exposed to radiation from nuclear medicine and CT scans. These procedures are necessary for your medical care and will occur even if you do not participate in this study. The radiation dose estimate that you will receive is equal to or less than the radiation exposure allowed to be received by a radiation worker for 3 years. The principal risk associated with a radiation dose is the possibility of developing a radiation-induced cancer later in life. Although the risk from radiation is cumulative, it is not expected to adversely affect your condition or treatment. The Emory University Radiation Safety Committee has reviewed and approved the use of radiation in this research study.

Will I benefit directly from the study?

This study is not designed to benefit you directly. Your cancer may improve while you are in this study but it may not, and it may even get worse. This study is designed to learn more about the combination of pembrolizumab and cabozantinib in squamous cell cancer of the head and neck. The study results may be used to help others in the future.

Will I be compensated for my time and effort?

You will not be offered compensation for being in this study.

Optional Tissue Samples for Future Research

Researchers are trying to learn more about cancer, diabetes, and other health problems. Much of this research is done using samples from your tissue, blood, urine, or other fluids. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure health problems.

If you choose to take part in this study, the study doctor for the main study would like to collect unused samples of your tumor and blood to be stored in the Winship tissue bank for future biomarker studies.

What are my other options?

If you decide not to enter this study, there is care available to you outside of this research study.

1- Participate in another research study
2- Receive pembrolizumab or a similar drug as part of the standard of care
3- Receive other standard chemotherapy drugs
4- Decide not to get treatment and opt for hospice care.

The study doctor will discuss these with you. You do not have to be in this study to be treated for cancer.

Taking part in this study, however, may make you unable to participate in some other research studies, if they exclude people who have taken certain treatments. You should discuss this with the researchers if you have concerns. You may wish to research other study options at websites like clinicaltrials.gov and ResearchMatch.org.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information

De-identified data from this study may be shared with the research community at large to advance science and health. Data from this study may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Medical Record

If you have been an Emory Healthcare patient before, then you already have an Emory Healthcare medical record. If you have never been an Emory Healthcare patient, you do not have one. An

Emory Healthcare medical record will be made for you if an Emory provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory Healthcare medical record you have now or any time during the study.

Emory Healthcare may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory Healthcare medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record.

Tests and procedures done at non-Emory places may not become part of your Emory medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury

If you get ill or injured from being in the study, Emory will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Nabil Saba at telephone number [redacted]. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured as a direct result from defects in the study drug, the study sponsor will pay the costs for your medical treatment of the illness or injury.

If you have Medicare or Medicaid: the sponsor may need information about your identity and your study treatment to give to the government agencies that run these programs.

Your insurance will be billed for any costs of medical treatment for your injury or illness that the sponsor does not pay. Your insurer may be told that you are in a research study. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

Emory has not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. The only exception to this policy is if it is proved that your injury or illness is directly caused by the negligence of an Emory or study sponsor employee.

Costs

The study sponsor will pay for certain items and services that you may receive if you take part in this study. Exelixis, the study supporter, will be providing the study drug for no cost. Additionally, the study sponsor will cover the cost of certain study related tests.

You will have to pay for the items or services for which the study sponsor does not pay. The sponsor will not pay for your regular medical care. If you have insurance, Emory will submit claims to your insurance for items and services that the sponsor does not cover. Emory will send in only those

claims for items and services that it reasonably believes your insurance will pay and that the sponsor has not paid.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory and the sponsor will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the main study and for any optional studies in which you may choose to participate.

Main Study

PHI that Will be Used/Disclosed:

The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information. We will use and disclose your PHI for the administration and payment of any costs relating to subject injury from the study.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- Dr. Nabil F. Saba is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- Exelixis Inc is the study supporter.
- The research team and the Sponsor may use and disclose your PHI, including disclosure to insurance carriers to administer payment for subject injury.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.

  - Government agencies that regulate the research including: Food and Drug Administration.
  - Public health agencies.
  - Research monitors and reviewer.
  - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Optional Study: Future Use of Patient Samples for Biomarker Studies

PHI That Will be Used/Disclosed for Optional Study:
The PHI that we will use and/or disclose (share) for the optional storage and future research use of your PHI includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for which your PHI will be Used/Disclosed for Optional Study:
We will use and disclose your PHI for the conduct and oversight of the optional storage and future research use of your PHI including the administration and payment of any costs relating to subject injury.

Authorization for This Use of PHI is Required to Participate in Optional Study, but Not in Main Study:
You do not have to authorize the use and disclosure of your PHI. If you do not authorize the use and disclosure of your PHI for the optional study, then you may not participate in the optional research study. You can still be in the main research study even if you don't participate in the optional study.

People Who Will Use/Disclose Your PHI for Optional Study:
The following people and groups will use and disclose your PHI in connection with the optional storage and future research use of your PHI:

- The same people and groups who will use and disclose your PHI for the Main Study will also do so in connection with the optional research study/storage of PHI for future research.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

Nabil F. Saba, MD
Winship Cancer Institute, Emory University
1365-C Clifton Road, NE
Atlanta, GA 30322

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the main study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information
Contact Dr. Nabil F. Saba, MD at [redacted]:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at [redacted]:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent and Authorization

Consent and HIPAA Authorization for Optional Study/Studies:
Please initial below if you opt to participate in and authorize use and disclosure of your PHI in the optional study previously described:

Samples for Future Use of Patient Samples for Biomarker Studies _____Initials

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TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study, and any optional studies you initialed above. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____
Name of Subject

_____ _____ ____:____ am / pm
Signature of Subject (18 or older and able to consent) Date Time (please circle)

TO BE FILLED OUT BY STUDY TEAM ONLY

_____
Name of Person Conducting Informed Consent Discussion

_____ _____ ____:____ am / pm
Signature of Person Conducting Informed Consent Discussion Date Time (please circle)