INFORMED CONSENT DOCUMENT

Project Title: Cabozantinib and Pembrolizumab as a Front-line Therapy for Advanced Metastatic Melanoma

Principal Investigator: Yousef Zakharia, MD

Research Team Contact: Yousef Zakharia, MD
319-356-4200 (or 319-356-1616 after 5:00 pm or on weekends)

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you are an adult with stage III or stage IV advanced melanoma that cannot be removed completely by surgery.

The purpose of this research study is to find the dose of cabozantinib that, when given in combination with the drug pembrolizumab, results in the best outcomes for your melanoma.

Cabozantinib is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration (FDA). Pembrolizumab is approved by the FDA for the treatment of metastatic melanoma.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 62 people will take part in this study conducted by investigators at the University of Iowa.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, you will receive treatment with cabozantinib and pembrolizumab for up to two years or until your disease progresses or you have unacceptable side effects. You will have visits every 3 weeks for a physical exam, labs and the pembrolizumab infusion. At some visits this will include an ECG and CT imaging as well. These visits will last from 3-4 hours.

Once study treatment has ended, you will have an end of treatment visit and be followed every 3 months for 2 years, every 6 months for 3 more years, then yearly.

WHAT WILL HAPPEN DURING THIS STUDY?

The study will be done in 2 phases. The Phase 1b portion of the study will establish the best dose of cabozantinib in combination with pembrolizumab and assess how safe and well-tolerated the drug combination is. The Phase 2 portion of the study will use the dose that was established in the Phase 1b portion of the study and will continue to evaluate the effectiveness of the drug combination. You will only participate in one of the two phases in this study. Study treatment will be administered in cycles. For this study, one cycle is 21 days.

Before you begin study treatment

You will need to sign the Informed Consent document and have a few tests done to see if you are eligible for this research study. During this visit the following procedures/assessments will occur:

- Review of your medical history, including medications you're taking
- Physical exam, including vital signs, height and weight
- Baseline daily stool count
- Triplicate ECG: you will have 3 ECGs at least 2 minutes apart.
- Echocardiogram or multi-gated acquisition scan (MUGA): this is a test that shows if there are problems with the way your heart is pumping.
- Pregnancy test for women of childbearing potential
- Blood draw to check the functioning of your blood, bone marrow, liver, kidneys, pancreas and thyroid
- Urinalysis
- Hepatitis B & C if your physician feels you are at a higher risk for these infections and you haven't been tested before
- CT or MRI scan of the chest, abdomen and pelvis
- Brain MRI if your physician feels this is needed
- Blood draw for future biomarker testing – done for research only (only if you are in Phase 2)
- Optional tumor biopsy for select patients (only if you are in Phase 2)

Study Treatment

If you are eligible and agree to participate in this study, you will take cabozantinib by mouth once daily.

Cabozantinib must be taken on an empty stomach. You should not eat for at least 2 hours before and at least 1 hour after taking cabozantinib. You should take the cabozantinib at approximately the same time every day. If you miss a dose, you may take it only if it is within 12 hours of when the missed dose should have been taken. The missed dose should not be made up if it is within 12 hours of the next scheduled dose.

Cabozantinib tablets should be swallowed whole with at least 8 ounces of water. The tablets should not be crushed. You should avoid consuming grapefruit, grapefruit juice, Seville oranges and their products while taking cabozantinib.

Day 1 of every ODD numbered Cycle (1, 3, 5, 7, 9 etc.):

- Physical exam, including vital signs and weight
- Blood draw to check the functioning of your blood, bone marrow, liver and kidneys
- Urinalysis
- CT scan of the chest, abdomen and pelvis and ECG (every 12 weeks)

- Review of your pill diary / pill count
- Administration of Cabozantinib - daily
- Administration of Pembrolizumab on Day 1 of each cycle through a vein in your arm

Day 1 of every EVEN numbered Cycle (2, 4, 6, 8, etc.):

- Physical exam, including vital signs and weight
- Blood draw to check the functioning of your blood, bone marrow, liver, kidneys and thyroid
- Urinalysis
- CT or MRI scan of the chest, abdomen and pelvis and ECG (every 12 weeks)
- Review of your pill diary / pill count
- Administration of Cabozantinib - daily
- Administration of Pembrolizumab on Day 1 of each cycle through a vein in your arm

A few additional procedures will also be conducted outside of the time points stated above. These include:

- Optional tumor biopsy at 7 weeks (+/- 1 week) and at disease progression (only if you are in Phase 2). You will have a chance to make this choice at the end of the Informed Consent Form.
- Research blood for future biomarker testing at week 7 (+/- 1 week) and at disease progression (only if you are in Phase 2).

End of Treatment visit:

- Physical exam, including vital signs and weight
- Single ECG
- Blood draw to check the functioning of your bone marrow, liver, kidneys and thyroid
- Urinalysis
- CT or MRI scan of the chest, abdomen and pelvis (every 12 weeks)
- Review of your pill diary / pill count

Follow-Up:

You will be followed every 3 months for 2 years, every 6 months for 3 years, then yearly. Follow-Up will be done by clinic visits, telephone contact, and / or correspondence with treating physicians.

Tissue/Blood/Data Storage for Future Use

As part of this study, we are obtaining blood and tissue samples from you. We would like to study your blood and tissue samples in the future, after this study is over. Other qualified researchers who obtain proper permission may gain access to your sample and/or data for use in approved research studies that may or may not be related to in the purpose of this study.

Your blood samples will not be used for research involving whole genome sequencing.

The tests we might want to use to study your blood and tissue samples may not even exist at this time. Therefore, we are asking for your permission to store your blood and tissue samples so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding melanoma, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your blood and tissue samples might be used to develop products tests, or discoveries that could be patented and licensed. In some instances, these may have potential

commercial value and may be developed by the Investigators, University of Iowa, commercial companies, organizations funding this research, or others that may not be working directly with this research team. However, donors of blood and tissue samples do not retain any property rights to the materials. Therefore, there are no plans to provide financial compensation to you should this occur.

Your blood and tissue samples will be stored *with a code which may be linked to your name and medical record number.* If you agree now to future use of your blood and tissue samples but decide in the future that you would like to have it removed from future research, you should contact Yousef Zakharia, MD at 319-384-8076. However, if some research with your blood and tissue samples has already been completed, the information from that research may still be used. This choice can be made at the end of this consent document.

WILL I BE NOTIFIED IF TESTING DONE ON MY BLOOD OR TISSUE SAMPLES RESULT IN AN UNEXPECTED FINDING?

We may learn things about you from the study activities which could be important to your health or to your treatment. If this happens, you can decide whether you want this information to be provided to you. If you choose to have this shared, you will be informed of any unexpected findings of possible clinical significance that may be discovered during review of results from your blood samples. The results from the blood and tissue samples we collect in this research study are not the same quality as what you would receive as part of your health care. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as feeling worried about a finding for which no treatment is available). We will be looking at how any mutations in your sample correspond with how you respond to treatment. Your study doctor would be able to give any information about the potential mutations to you at a study visit. Your choice about receiving this information can be made at the end of this consent document.

The blood and tissue samples will not be reviewed by a physician who normally reads such results, and they will inform us if there are any unexpected findings. We will provide you with this information so that you may discuss it with your primary care physician. However, if you believe you are having symptoms that may require care prior to receiving any information from this study, you should contact your primary care physician. The study team/study will not cover the costs of any follow-up consultations or actions.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Possible Risks of Cabozantinib:

VERY COMMON, SOME MAY BE SERIOUS (in 100 people receiving cabozantinib, more than 10 and up to 100):

- Diarrhea
- Fatigue
- Loss of appetite
- Nausea
- Blisters, rash, or pain in hands or feet

- Weight loss
- High blood pressure
- Vomiting
- Changes in taste
- Change in voice
- Mouth and throat sores or swelling
- Weakness
- Inflammation of mucus membranes
- Changes in blood tests used to monitor the liver, which may indicate liver damage
- Constipation
- Rash
- Alteration of thyroid function tests
- Abdominal pain
- Hair color changes or hair loss

OCCASIONAL, SOME MAY BE SERIOUS (greater than 1 in 100, but less than 1 in 10):

- Dry mouth
- Upset stomach or indigestion
- Dry skin
- Decreased amounts of red blood cells (anemia), which may cause feelings of tiredness or shortness of breath
- Mouth or throat pain
- Decreased amounts of magnesium or phosphorus in the blood
- Shortness of breath
- Decreased platelet counts, which increases the risk of bleeding or make bleeding more difficult to stop
- Pain in extremities
- Dizziness
- Headache
- Protein in the urine, which may indicate kidney damage
- Muscle spasm
- Decreased white blood cell counts, which may increase chances of infection
- Decreased or increased amounts of potassium in the blood
- Decreased amounts of calcium or sodium in the blood
- Dehydration
- Increased amounts of pancreas enzymes in the blood, which may indicate damage to the pancreas
- Stomach acid coming up from the stomach into the esophagus
- Difficulty swallowing
- Swelling of the limb(s)
- Cough
- Increased levels of bilirubin in the blood, which may indicate complications with the liver
- Pain in a joint or muscle
- Change in the feeling of touch

- Decreased level of albumin in the blood
- Abnormal thickening of the outer layer of the skin
- Fever
- Blood clot in a large vein, usually in the leg
- Muscle weakness
- Hemorrhoids
- Increased levels of creatinine in the blood, which may indicate complications with the kidneys
- Confusion and disorientation
- Dermatitis acneiform, a type of acne
- Bleeding, including bleeding from stomach or intestines which may look like coffee grounds or black sticky bowel movements, and bleeding within the brain
- Ulcer
- Fungal infections including mouth, lung, and other locations
- Blood clot that travels from a vein to the lung

UNCOMMON (Greater than or equal to 1 in 1000, but less than 1 in 100):

- Tear or inflammation in skin that lines the anus
- Feelings of unease or fear
- Re-opening of wounds after surgery
- Pneumonia and inflammation of the lungs
- Reduced kidney function
- Destruction of bone tissue, in particular, bone in the jaw
- Uncoordinated movements
- Decreased brain function or decreased alertness and ability to think
- Heart failure
- Liver failure
- Seizure
- Loss of consciousness, fainting episode
- Heart attack
- Inflammation of the intestine, appendix, gall bladder or thin tissue lining the inner wall of the abdomen and most of the abdominal organs
- Rapid heart rhythm
- Abnormal electrical activity in the heart that could cause a potentially serious change in heart rhythm
- Abnormal opening between two organs or from an organ to the outside of the body
- Abscesses (infected cavities filled with pus)
- Blood clot in an artery
- Decrease in all blood counts (red blood cells, white blood cells and platelets)
- Chest discomfort originating from the heart
- Clouding of the lens in the eye that affects vision
- Damage to skeletal muscle tissue
- Gallstones
- Respiratory failure
- Holes in the stomach or intestines

- Infections
- Stroke / mini stroke
- Temporary paralysis of the intestines
- Throat swelling

RARE AND SERIOUS (Greater than or equal to1 in 10,000 but less than 1 in 1000):

- Air in the chest between lungs and chest wall
- Allergic reaction
- Anemia caused by destruction of red blood cells
- Blocked intestines
- Brain dysfunction caused by brain
- Cancer of the mouth or skin
- Damage to the outermost surface of the eye
- Inflammation and blockage of channels that carry bile from the liver
- Severe swelling of the mouth, lips, tongue, eyes and throat, or difficulty swallowing or breathing
- Very high blood pressure that comes on suddenly and quickly and which can lead to serious injury to the heart and brain

Possible Risks of Pembrolizumab:

Pembrolizumab is a drug that has been extensively studied in patients with a variety of cancers. It has been approved by the FDA for use in patients with certain types of melanomas, lung cancer, head and neck squamous cell cancer, bladder cancer and Hodgkin lymphoma. Please refer to the KEYTRUDA® (pembrolizumab) U.S. FDA approved medication guide and label for all associated risks. Your doctor can explain these risks to you. Information about KEYTRUDA® can be found on the website https://www.keytruda.com.

Pembrolizumab has been associated with a variety of autoimmune disorders including:

- Pneumonitis (inflammation in the lungs)
- Colitis (inflammation of the colon)
- Hepatitis (inflammation of the liver)
- Nephritis (inflammation of the kidneys)
- Neuritis or myositis (inflammation of the nerves or muscles, including pain, weakness, or temporary paralysis)
- Endocrinopathies
  - Hypophysitis (inflammation of the pituitary gland)
  - Thyroid disorders such as hypothyroidism (low thyroid hormone)
  - Adrenal failure
  - Type 1 diabetes mellitus

Side effects that have been associated with pembrolizumab include the following, some of which can be life threatening:

- Allergic and similar reactions, some of which may be severe skin reactions such as Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis.
- Inflammation in certain organs including the lungs, pancreas, large intestine, liver, pituitary gland, thyroid gland, kidneys, and/or brain (such as encephalitis) or an inflammatory disease

known as sarcoidosis which affects multiple organs in the body, most commonly the lungs, lymph nodes, eyes and skin.
- Elevation of blood sugar levels and symptoms of diabetes.
- Fatigue, itching; diarrhea, decreased appetite, rash, fever, cough, difficulty breathing, joint pain, constipation, and nausea.
- Infusion related reactions can develop which may result in redness/flushing, sweating, rash, difficulty breathing, nausea, and/ or severe allergic reaction that can lead to death.
- Inflammation and weakening of the heart (myocarditis)
- Pancreatitis
- For women who become pregnant, potential toxicity to the fetus, miscarriage or birth defects.
- 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.

In addition to the above, if you have had an allogeneic stem cell transplant (a procedure in which a person receives blood forming stem cells from a donor), you may experience graft versus host disease (GvHD), which may include diarrhea, skin rashes, and liver damage, after receiving pembrolizumab. Sometimes this condition can lead to death.

Women Capable of Becoming Pregnant:

If you are a woman who is capable of becoming pregnant, we will ask you to have a pregnancy test before beginning this study. You must use effective birth control methods and try not to become pregnant while participating in this study. If you become pregnant, there may be unknown risks to your fetus, or risks to your fetus that we did not anticipate, associated with being in the study. There may be long-term effects of the treatment being studied that could increase the risk of harm to an unborn child. If you believe or know you have become pregnant while participating in this research study, please contact Dr. Yousef Zakharia at 319-356-4200 as soon as possible.

Risks from drawing blood:

Drawing blood may cause pain, bruising, bleeding or infection at the site of the needle stick. Care will be taken to avoid these complications.

Biopsy (for Phase 2 only):

The risks of the biopsy include bleeding, bruising or swelling. There is a rare risk of infection.

Testing for Reportable Diseases:

If you decide to participate in this study, we may test you for Hepatitis B or Hepatitis C. The results of the test could indicate that you have Hepatitis B or Hepatitis C. If that happens, we will refer you to a doctor who specializes in treating Hepatitis. We will make every effort to keep your personal information confidential. However, we are required by law to report positive tests to the Iowa Department of Public Health. Becoming aware of a diagnosis of Hepatitis B or Hepatitis C could have serious personal and/or social consequences, including difficulty obtaining health insurance or employment. For more information about the risks of Hepatitis B or Hepatitis C testing, please talk to your study doctor.

MRI Scan (Only if your physician feels this is needed):

An MRI scanner takes pictures of the inside of your body by using a magnetic field and radio waves. Because the MRI scanner contains a very strong magnet, you may not be able to have the MRI if you have certain kinds of metal in your body (for example, a heart pacemaker, a metal plate, certain types of heart valves or brain aneurysm clips). Someone will ask you questions about this before you have the MRI.

The MRI scanner is a large machine that contains a hollow tube. You will be asked to lie on your back on a special table that slides into the tube. The sides of the tube will be close to your body so you may feel uncomfortable or anxious while inside the scanner ("claustrophobia"). You will be able to talk with the MRI staff through a speaker system and you can tell them to stop the scan at any time.

The scanner makes a loud hammering noise which has caused hearing loss in a very small number of patients. You will be given earplugs to reduce this risk.

WHAT ARE THE BENEFITS OF THIS STUDY?

We don't know if you will benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because of the information gained in finding a better way to treat advanced metastatic melanoma.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could receive standard treatment for your disease or choose to be in a different clinical trial if one is available.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You may have additional costs for being in this research study.

The following will be provided by the study at no charge:

- Study drug (Cabozantinib)
- The blood tests and optional tumor biopsies done for research purposes only. These are not clinical tests and are provided by the study.

You (and your insurance company) will be charged for:

- Infusion of the pembrolizumab
- Any imaging, including standard MRI or CT scans. This is standard for your cancer.
- Your doctors' visits and any ordered blood tests. You would have those normally for your cancer care.

You and/or your medical/hospital insurance carrier will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

Exelixis, Inc. is funding this research study and providing the study drug cabozantinib. This means that the University of Iowa is receiving payments from Exelixis, Inc. to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from Exelixis, Inc. for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
- The University of Iowa does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.
- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Federal government regulatory agencies,
- The U.S. Food and Drug Administration and the sponsor, Exelixis, Inc.
- The sponsor Exelixis, Inc. may also inspect any part of your medical record for the purposes of auditing the conduct of the study
- Auditing departments of the University of Iowa, and
- The University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, your research data will be identified by a code rather than your name. Only the PI and designated research team members will have access to the list linking a code to a name. Electronic data will be kept on a password protected computer and hard copy records will be kept in a locked room when no one is present. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

The University of Iowa Hospitals and Clinics generally requires that we document your participation in research occurring in a University of Iowa Health Care facility. This documentation will be in either your medical record or a database maintained on behalf of the institution reflecting that you are participating in this study. The information included will provide contact information for the research team as well as information about the risks associated with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

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

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires your health care provider to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research and for your treatment. Once your health care provider has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff, the Data and Safety Monitoring Board of the Holden Comprehensive Cancer Center, the Sponsor, Exelixis, Inc. The sponsor, Exelixis, Inc. may also inspect any part of your medical record for the purposes of auditing the conduct of the study.

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes your health care provider to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to:

Yousef Zakharia, MD
University of Iowa Hospitals & Clinics
200 Hawkins Drive, C32 GH
Iowa City IA 52242

However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I Decide to Drop Out of the Study?

You may withdraw from the study at any time. Leaving the study early may cause you to experience harms or discomforts. If you decide to leave the study early, we will ask you to return for the End of Treatment visit within 30 days (+/- 7 days) of the last dose of the study drugs.

Will I Receive New Information About the Study while Participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can Someone Else End my Participation in this Study?

Under certain circumstances, the researchers or Exelixis, Inc. might decide to end your participation in this research study earlier than planned. A few reasons this could happen include: your cancer has progressed, the study drug will no longer be supplied, your inability to adhere to the protocol schedule, you have unacceptable adverse experiences, it is no longer in your best interest to participate in the trial, or the trial is no longer being funded.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Dr. Yousef Zakharia at 319-356-4200. If you experience a research-related injury, please contact: Dr. Yousef Zakharia at 319-356-4200. If it is after 5:00 pm, or on a weekend, call 319-356-1616 and ask for the Hematology/Oncology Fellow on call.

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

Photographs
If study treatment-related skin changes occur (eg, rash, hand-foot syndrome), the study doctor may request that additional assessments be conducted with your consent. This may include digital photographs of the skin changes and may be repeated until the skin changes resolve. The photographs, like other research data may be sent to Exelixis and its partners or designees for review. The photographs will be destroyed approximately 15 years after the study ends.

____ Yes ____ No I give permission to take photographs of me during this study. Please initial your choice.

Optional Specimen Collection for Biomarker Testing
10-15 subjects in the Phase 2 portion of this study will be asked to provide their consent for a tumor biopsy for additional Biomarker testing.

____ Yes ____ No I give permission to the researchers to obtain fresh tumor tissue for biomarker testing at 7 weeks (+/- 1 week) and at time of disease progression. Please initial your choice.

Tissue/Blood/Data Storage for Future Use

____ Yes ____ No My blood and tissue samples may be stored/shared for future biomarker research.

Notification of unexpected findings in my blood or tissue samples

Please initial one of the following options:

_____ Yes, I want to be provided with this information.

_____ No, I do NOT want to be provided with this information.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

Do not sign this form if today's date is on or after EXPIRATION DATE: 04/12/24.

_____ _____
(Signature of Subject) (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

Name (printed) _____

_____ _____
(Signature of Person who Obtained Consent) (Date)