Model Consent Form

Protocol: A Phase II Trial of Bevacizumab and Rucaparib in Recurrent Carcinoma of the Cervix or Endometrium

Study Sponsor: University of Oklahoma Health Sciences Center (OUHSC)

Funding Collaborator: Clovis Oncology

This is a clinical trial (a type of research study). Your study doctor will explain the clinical trial to you. Clinical trials include only patients who choose to take part in them. Please take your time to make your decision. You may discuss this with your family, friends and doctors. If you have any questions, you can ask your study doctor for more information at any time.

Clovis Oncology pharmaceutical company is providing the study medicine, rucaparib, free of charge and paying for certain study procedures.

Why Have I Been Asked To Participate In This Study?

You are being asked to take part in this trial/study because you have been diagnosed as having carcinoma of the cervix or endometrium.

Why Is This Study Being Done?

The purpose of this study is to find out what effects (good and bad) that combination treatment of rucaparib and bevacizumab has on you and others with persistent or recurrent cervical or endometrial cancer. This study is being done because currently there is no effective treatment for people with your condition. We will look to see if the medicine is helpful in shrinking cancers, keeping them from growing or spreading, or helping patients live longer. We will also collect information about any side effects and how you feel with the two medications.

What is the Status of the Drugs (Devices or Procedures) Involved in this Study?

Rucaparib is currently approved by the US Food and Drug Administration for treatment of patients with advanced ovarian cancer who have been treated with two or more chemotherapies; but is not approved for the disease in this study, so it is considered investigational in this study.

Bevacizumab is currently approved by the US Food and Drug Administration for treatment of patients with various types of cancer, but the combination of bevacizumab and rucaparib is not approved for the disease in this study, so it is considered investigational in this study.

How Many People Will Take Part In The Study?

About 100 people will take part in this study within four medical centers nationwide. About XX of these individuals will participate at this medical center.

What Is Involved In The Study?

If you take part in this study, you will have the following tests and procedures:

Before you begin the study
You will need to have the following exams, tests or procedures to find out if you can be treated in the study. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- Doctor's visit with examination to include a pelvic examination
- Blood work to measure blood counts, blood clot function, blood salt levels, and how well your liver and kidneys are working
- A pregnancy test if you are capable of becoming pregnant
- Urinalysis (examination of urine)
- CT scan or MRI of the chest, abdomen and pelvis to measure your tumor

You will need to have the following tests as part of the study. The following exams are not standard of care:

- Research blood draws
- Tumor biopsy
- ECG (electrocardiogram)

During the study
If the exams, tests and procedures show that you can be treated in the study, and you choose to take part, then you will need the following tests and procedures. They are part of regular cancer care**.**

- Doctor's visit with examination to include a pelvic examination every treatment cycle (typically every 3 weeks)
- Blood tests to measure blood counts, blood salt levels, and how well your liver and kidneys are working (as often as once 3 weekly, but may be weekly if you have blood cell counts decreased)
- Urinalysis (examination of urine) done once every treatment cycle (typically every 3 weeks)
- Repeat CT scans every other cycle (typically every 8 weeks).

You will receive treatment of rucaparib and bevacizumab until unacceptable toxicity or tumor progression.

- You will take rucaparib twice a day by mouth with 8 oz. (240 mL) of room temperature water; tablets should be swallowed whole without chewing. You should take rucaparib doses as close to 12 hours apart as possible, preferably at the same times every day. If you miss a dose (i.e., did not take it within 4 hours of the scheduled time), you should skip the missed dose and resume taking rucaparib with the next scheduled dose. Missed or vomited doses should not be made up.
    - You will also need to fill out a pill diary when you take your pills.
- You will receive bevacizumab by vein (IV) once each cycle on day 1 of the 21 day cycle.

On day 22, if your oncologist feels you may safely continue treatment, you will begin a new 21 day cycle.

After your treatments are completed:

To monitor your well-being and the status of your cancer, you will have these tests and procedures that are part of regular cancer care:

- Doctor's visit with examination which may include pelvic examination
  - every 3 months for two years
  - then every 6 months for three years
  - then every year thereafter
- Blood work if your physician feels they are necessary for monitoring
- CT scan or MRI at the end of the study as indicated by your doctor
- Urinalysis (examination of urine)

You will need to have the following tests as part of the study. The following exams are not standard of care:

- ECG (electrocardiogram)

How Long Will I Be In The Study?

You will be asked to take the study medicines as long as there is evidence that your tumor is not growing or spreading and you are not having any bad side effects. If there is no cancer on your scans after 6 cycles of treatment, you may continue with the study treatment for one more year.

After you have finished treatment, the study doctor will ask you to visit the office for follow-up exams at least every three months for the first two years and every six months for the next three years. After this, we would like to keep track of your medical condition for the rest of your life by calling you once a year to see how you are doing. Keeping in touch with you and checking on you every year helps us look at the long-term effects of the study medicines.

Can I Stop Being in the Study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study doctor if you are thinking about stopping, so any risks from the study treatment can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what other care and testing could be most helpful for you.

There may be anticipated circumstances under which your participation may be terminated by the investigator without regard to your consent.

- The doctor feels that it is safest for you.
- Your cancer or medical illnesses worsen.
- New information becomes available that suggests another treatment would be better for you
- You do not follow study requirements.
- The study is stopped by the sponsor.

What Are The Possible Side Effects, Risks and Discomforts of The Study?

You may have side effects from taking rucaparib or from the procedures used in this study. You should discuss these with the researcher and/or your regular doctor. Other drugs may be given to make side effects less serious and uncomfortable. Many side effects go away shortly after the

rucaparib and/or bevacizumab are stopped, but in some cases side effects can be serious or long lasting and permanent. The treatment or procedure may involve risks that are currently unforeseeable.

Side effects may vary from person to person, and can range from mild to very serious. If you have any side effects as a result of taking part in this study, tell your study doctor right away, even if you don't think they are due to the rucaparib.

Rucaparib Side Effects

Oral rucaparib is an experimental drug that may have side effects that cannot be predicted at this time. Rare or unknown side effects could possibly occur, including life-threatening events or death. If you experience certain side effects, the study doctor may decide to stop or lower your dose of rucaparib until you recover from the side effects.

The following is a list of reported side effects as well as other notable side effects considered to be possibly due to rucaparib, as reported by physicians about their patients who are taking rucaparib alone:

Very common (Occurring in 10% or more of patients)

- Nausea
- Feeling tired (known as fatigue or lethargy)
- Low blood counts, (red blood cells, white blood cells, and platelets). Sometimes fever occurs with the low blood counts. These low blood count effects may be more likely to occur after multiple cycles of treatment.
    - A low red blood cell count may make you feel tired or dizzy. If you feel dizzy while taking rucaparib, you should avoid potentially hazardous tasks such as driving or operating machinery.
    - A low white blood cell count puts you at higher risk for bacterial or viral infections. Having a high temperature or fever while your white blood cell count is low is a medical emergency and you must proceed to the nearest emergency room as soon as possible.
    - A low platelet count affects the ability of your blood to clot and could lead to bleeding events. Symptoms include but are not limited to easy bruising, prolonged bleeding from cuts, blood in stools or urine, or nose bleeding.
- A low phosphate level in your blood. Usually there are no symptoms, but if the levels are critically low, you may notice trouble breathing, confusion, muscle weakness, and/or irritability.
- Increase in cholesterol. If your cholesterol increases significantly, your doctor may prescribe a medicine to lower your cholesterol level.
- Changes in kidney and liver function blood tests. These changes will be evaluated by your study doctor along with any other side effects that you are experiencing as well as other test results.
- Changes in your sense of taste
- Stomach-related effects such as constipation, vomiting, diarrhea, decreased appetite, stomach pain (epigastric pain), and indigestion.
- Difficulty breathing (dyspnea)
- Dizziness

- Photosensitivity reaction
  - It is possible that rucaparib may make your skin and eyes more sensitive to sunlight. You should take all of the usual sun protection precautions when going outside. It is advised that you avoid excessive sun exposure, wear protective clothing (including wearing a hat and sunglasses), and use sunscreens regularly (sun protection factor 50 or greater).
- Fever sometimes can occur independent of a low blood count. If you experience an elevation of your temperature, please refer to your study doctor for fever management.
- Difficulty sleeping

Common (Occurring in 1% to less than 10% of patients)

- Upper Airway Infection (like the common cold)
  - You may experience infections involving the nose, pharynx, larynx, and sinuses. Symptoms include a blocked (congested) nose, a runny nose, and sneezing. You may also have clear discharge (mucus) from the nose. You may feel generally unwell and may also be associated with fever. Treatment is usually supportive but if symptoms persist, please inform your doctor.

Uncommon (Occurring in 0.1% up to less than 1% of patients)

- Myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML)
  - Effects possibly related to rucaparib, but whose causal link has not been formally established, have been reported in a very small number of patients treated with rucaparib during the safety period (while on treatment with rucaparib and 28 days after last dose). MDS is a pre-cancerous condition where the bone marrow is not as good at producing blood cells (red and/or white blood cells and/or platelets). People with MDS need transfusions (red blood cells and/or platelets) and/or other treatments. In some cases, MDS will progress to AML, which is a cancer of the bone marrow where more abnormal and immature white blood cells (also called blasts) are made than normal white blood cells. People with AML need treatment with chemotherapy and/or a bone marrow transplant. Patients may develop AML without first being diagnosed with MDS.
  - Events of MDS and AML have also been reported with PARP inhibitors similar to rucaparib. At this time, it is not known whether rucaparib or other PARP inhibitors cause MDS or AML, or if these developed as a result of previous chemotherapy these patients received. Your study doctor will closely monitor your blood cell levels during treatment. If he/she has any concerns about your blood counts you may be asked to have a biopsy of your bone marrow.

Allergic Reactions

As with any drug, it is possible that you could have allergic reactions to rucaparib, such as itching, skin rash, facial swelling, and/or a severe or sudden drop in blood pressure. A sudden drop in blood pressure could lead to shock with loss of consciousness and/or possible seizures, including the possibility of death. If you have any of the above symptoms, seek medical attention right away.

Possible Side Effects of Bevacizumab

The following is a list of the most commonly-reported side effects and other notable side effects considered to be possibly due to bevacizumab, as reported by physicians about their patients who are taking bevacizumab alone:

Likely (Occurring in 20% or more of patients)

- High blood pressure which may cause headache or blurred vision
- Low appetite, nausea, vomiting, constipation or diarrhea

Less Likely (Occurring in 4-20% of patients)

- Anemia which may require blood transfusion
- Low white cell count that may increase the risk of infection
- Infection, including collection of pus in the belly or rectum
- Abnormal heartbeat which may cause palpitations or fainting
- Pain in the belly, rectum, chest, joints, muscles, or tumor
- Internal bleeding (predominantly tumor-associated) which may cause black tarry stool, blood in vomit, coughing up of blood, or blood in urine
- Bleeding from other sites, including the vagina, gingiva or nose
- Blockage of internal organs which may cause vomiting or inability to pass stool
- Sores in mouth
- Allergic reaction during or after infusion of bevacizumab which may cause fever, chills, rash, itching, hives, low blood pressure, wheezing, shortness of breath, swelling of the face or throat
- Delay in healing of wounds or spontaneous opening of wounds
- Weight loss, tiredness, or dizziness or dehydration or muscle weakness
- Damage to the jawbone which may cause loss of teeth or loss of motion
- Headache, or excess tearing
- Numbness, tingling, or pain in the fingers or toes
- Hoarseness, stuffy nose, or cough
- Dry skin, or swelling and redness of the skin
- Blood clot in limbs or lungs which may cause swelling, pain, shortness of breath
- Leakage of protein in the urine, which can rarely lead to damage to the kidney
- Clots in the arteries, causing stroke (which may cause paralysis or weakness) or heart attack (which may cause chest pain or shortness of breath). This risk is significantly increased in patients who are elderly or with history of diabetes
- Hypomagnesemia or hyponatremia (a low level of magnesium or sodium in the blood)

Uncommon (Occurring in <3% of patients)

- Heart failure which may cause shortness of breath, swelling of ankles, or tiredness
- Bowel perforation (a tear in the bowel) that can cause pain or bleeding and require surgery to repair
- Gall-bladder perforation (a tear in gall-bladder) that can cause pain and require surgery to repair
- A tear or hole (fistula) in internal organs such as the nose, throat, lungs, esophagus, rectum, or vagina. These conditions may cause serious infections or bleeding and require surgery to repair
- Sores in the throat
- Flesh-eating bacteria syndrome, an infection in the deep layers of skin

- Bleeding in the tumor, brain, belly, or lungs which may cause confusion, blood in stool or coughing up blood
- Brain damage which may cause headache, seizure, blindness (also known as Reversible Posterior Leukoencephalopathy Syndrome)
- Kidney damage which may require dialysis
- Redness, pain or peeling of palms and soles
- Antibody development (anti-bevacizumab antibody)

Rare but potentially serious (occur in less than 1% of patients taking bevacizumab alone or in combination with other anti-cancer drugs)

- Anaphylaxis (a severe, potentially life-threatening allergic reaction)
- Acute myocardial infarction (heart attack)
- Cerebral infarction (stroke)
- Hemolytic anemia (destruction of red blood cells causing anemia)
- Hypertensive crisis, hypertensive encephalopathy,
- Increased intraocular pressure, inflammation of eye, or permanent vision loss
- Intestinal necrosis (bowel tissue death likely due to loss of blood flow to the intestines)
- Pulmonary hypertension (high blood pressure in lung)
- Tracheoesophageal fistula (abnormal connection between the esophagus and the trachea)

Additional Notes on Possible Side Effects for Bevacizumab:

- Risk in pre-menopausal women: more likely to develop menopause when taking bevacizumab.
- Risk in children or adolescents: abnormal bone changes which may interfere with growth.

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

Additional Risks or Discomforts

Procedure to Collect A Tumor Tissue Sample:
During the screening phase, if an archived tumor sample is not available, you will undergo a procedure to collect a sample of your tumor (called a biopsy), unless the biopsy procedure is considered unsafe by the study doctor or if the study doctor is unable to collect a sample, which will be used for biomarker research. **You must indicate if you agree or do not agree to the biopsy procedures during screening by initialing at the end of this consent form.**

The risk and discomfort to you depends upon the site of the biopsy. Since a larger needle is being inserted into your body under local anesthesia, there is a risk of some pain or infection. Bleeding, bruising or swelling could also occur. Ask the study doctor to tell you about more specific biopsy risks based on the site of your biopsy.

Blood Sampling:

Having blood drawn from a vein in your body may cause some pain, redness, or bruising where the needle is inserted. An infection is also possible, but rare. If you feel faint while having your blood drawn, you should sit or lie down to avoid falling.

Electrocardiogram (ECG):
The ECG test is a recording of the electrical activity of your heart. The sticky pads used may be cold when applied and your skin may react to the sticky patches that attach the detectors (electrodes) to the chest for ECG. This skin irritation usually disappears when the patches are removed. If the hair under the patches needs to be shaved, irritation from shaving also could occur.

CT and MRI Scans:
Computed tomography (CT) scans use x-ray radiation. The amount of radiation you will receive during a CT scan is small, but the more radiation you receive over the course of your life, the more likely it is that the cells in your body may change or that you develop a new cancer. Some CT scans require you to take a "contrast solution" injected into a vein. It is possible that the contrast solution may cause you to have nausea, vomiting, itching, or skin rash. In rare cases, it may cause your throat to swell and make it hard to breathe. These may be signs of an allergic reaction so tell the study doctor right away if you have any of these side effects. You may have some discomfort from lying still in an enclosed space for a prolonged period of time.

Sometimes a magnetic resonance imaging (MRI) scan is done in patients with allergies to the contrast solution used in a CT scan. An MRI does not use x-ray radiation, but it takes a little longer and patients sometimes have to lie in a more enclosed space than with a CT scan. A contrast solution may be injected into your vein before the scan is done to help the doctor see the tumor more clearly.

Reproductive risks:
Treatment with rucaparib may involve risks that are currently unforeseeable to a fetus, embryo, or unborn child. You cannot participate in this study if you are pregnant, or if you are thinking about becoming pregnant. You should not nurse (breast feed) a baby while in this study because the study drug may enter breast milk and possibly harm your child.

If you are of childbearing potential, you must agree to undergo monthly serum pregnancy testing and use highly effective birth control while you are taking rucaparib and for 6 months afterward. Highly effective birth control is considered to be a method with a less than 1% per year failure rate and is defined in this study as established use of progesterone-only injectable or implantable contraceptives (e.g. Depo Provera, Implanon, Nexplanon), placement of an intrauterine device (IUD) or intrauterine system (IUS), surgical sterilization, or true, complete (as opposed to periodic) abstinence. If this applies to you, please discuss your plan for birth control with the investigator or study staff.

If you become pregnant or suspect that you are pregnant during this study, you should immediately inform the study personnel. If you become pregnant or suspect that you are pregnant while on this study, tell the study doctor immediately; the study doctor will perform a pregnancy test. The study drug may be discontinued until the result of the pregnancy test is known. If pregnancy is confirmed, you may be withdrawn from the study. The study doctor will assist you in getting obstetrical care at your cost. Payment for all aspects of obstetrical, child, or related care will be your responsibility.

If you think you might want to have a child after taking part in this study, you should also talk with the study doctor about whether your eggs should be stored before you start study treatment. The cost of storing your eggs is not covered by this study. If you get pregnant at any time during this study or within 6 months after taking your last dose of study drug, tell the study doctor right away and you will need to stop taking rucaparib immediately (if you are taking rucaparib at the time). You may be asked for information about your health and the baby's health to see how the pregnancy turned out.

Are There Benefits to Taking Part in The Study?
If you agree to take part in this study, there may or may not be direct medical benefit to you. We hope that the information learned from this study will benefit other patients with this disease in the future.

What Other Options Are There?
If you decide not to take part in this study, you have other choices for your care. For example:

- You may choose to receive no therapy at this time and receive only care to help you feel more comfortable.
- You may choose to take part in a different research study, if one is available

Please talk to your regular doctor about these and other options.

What about Confidentiality?
Efforts will be made to keep your personal information confidential. You will not be identifiable by name or description in any reports or publications about this study. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. You will be asked to sign a separate authorization form for use or sharing of your protected health information.

There are organizations outside the insert site name that may inspect and/or copy your research records for quality assurance and data analysis. These organizations include the study Sponsor and its representatives, the US Food & Drug Administration, and other regulatory agencies, and Clovis Oncology and its representatives.

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

When the research results are published or discussed in conferences, no information will be included that reveals your identity. In a few rare situations, federal or state law requires disclosure of personal information.

What Are the Costs?
You and/or your health plan/insurance company will need to pay for some of the costs of treating your cancer in this study, including the cost of monitoring and managing the side effects of therapy.

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. You will be responsible for paying any deductibles, co-insurance, and co-payments as required under the terms of your insurance plan(s). Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

Rucaparib is an investigational drug and will be provided free of charge by Clovis Oncology. The tumor biopsy and related molecular assays which are specifically needed to check for the potential relationship with the effect of this medicine will be covered under the study. However, you or your insurance company will be required to pay for all expenses related to the administration of the drug and your other hospital care.

Bevacizumab is currently commercially available for cancer therapy. You or your insurance company will be required to pay for bevacizumab and all expenses related to the administration of the drug and your other hospital care.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://cancer.gov/clinicaltrials/understanding/insurance-coverage. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.

Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

Will I Be Paid For Participating in This Study?
You will not be paid for taking part in this study.

What if I am Injured or Become Ill While Participating in this Study?
In the case of injury or illness resulting from this study, emergency medical treatment is available. No funds have been set aside by the Sponsor to compensate you in the event of injury.

You will get medical treatment if you are injured as a result of taking part in this study. The study will not pay for medical treatment.

What Are My Rights As a Participant?
Taking part in this study is voluntary. You may choose not to participate. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

If you agree to participate and then decide against it, you can withdraw for any reason and leave the study at any time. However, at certain times during the treatment, it may be harmful for you to withdraw, so please be sure to discuss leaving the study with the principal investigator or your regular physician. You may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled.

We will provide you with any significant new findings developed during the course of the research that may affect your health, welfare, or willingness to continue your participation in this study.

You have the right to access the medical information that has been collected about you as a part of this research study. However, you may not have access to this medical information until the entire research study has completely finished. You consent to this temporary restriction.

Where Can I Get More Information?
You may call the National Cancer Institute's Cancer Information Service at:

1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615

You may also visit the NCI Web site at http://cancer.gov/

- For NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials/
- For NCI's general information about cancer, go to http://cancer.gov/cancerinfo/

You will get a copy of this form. If you want more information about this study, ask your study doctor.

GENERAL INFORMATION ABOUT THE COLLECTION AND USE OF SPECIMENS FOR RESEARCH
You are being asked to allow samples from your tumor and blood to be submitted and used in research. Such bodily materials are referred to as specimens and are very important in helping doctors and scientists learn more about caring for and treating people with cancer and other diseases. The use of specimens in scientific research can also help doctors and scientists understand why some people develop cancer and others don't, and why some people have cancers that respond or don't respond well to current therapies, for example.

The research that may be done with your specimens is not designed specifically to help you, but it may help others with cancer or other diseases in the future. Reports about research done with your specimens will not be given to you or your regular physicians, or be put in your health record. The research will not have an effect on your care.

When research is performed on specimens connected with clinical information about the person, including the person's disease and how the person responds to treatment, doctors and scientists can specifically study how to prevent, detect, treat and cure cancer and other diseases, or how to predict response to therapy, toxicities, recurrence and overall survival.

The Sponsor uses procedures designed to protect your privacy and confidentiality. The chance that information from your health records would be incorrectly released is very small, but you should be aware of this risk. To protect your privacy and confidentiality, the research investigators that study your specimens will never be given your name, address, phone number, Social Security number or any other personal information. In addition, your specimens will never be labeled with your name or other type of personal identifier. Your specimens will be labeled with a unique series of letters and numbers in order to keep track of the specimens. Research investigators receive specimens labeled only with these codes.

Your specimens will be used for research purposes and will not be sold. However, the research may help to develop new products and therapies in the future that could be patented and licensed. In any event, there are no plans to provide you with any direct financial compensation.

If you agree now that your tumor specimen and/or blood specimens can be submitted and used for this research study and/or future research, you can change your mind at any time. At that time, please contact the staff at your treating institution, typically your doctor or nurse, and tell them that you have changed your mind about allowing your specimens to be used for research.

SPECIFIC INFORMATION FOR THIS RESEARCH STUDY

Requirements

We would like to have your permission to have some of your tumor, if available, from a recent surgery. If you have not recently had surgery, we are requesting you undergo a biopsy to obtain a small piece of your tumor. The reason for this is to study your tumor and the effect of this treatment on it.

We are also asking participants to provide two teaspoons of blood one time to look at parts in the blood and how it relates to treatment response. This will be done when you enroll into the study.

Risks of genetic testing:

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information.

This law generally will protect you in the following ways:

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

Be aware that this Federal law does not protect you or your family against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Also, GINA does not prohibit discrimination of individuals with a genetic disorder that has been diagnosed. However, in order to do everything possible to keep this from happening, the results of this test will NOT be given to anyone outside the study staff. This means that it will not be made available to you, your family members, your private physician, your employer, your insurance company or any other party as allowed by law.

Whom Do I Call If I have Questions or Problems?

If you have questions, concerns, or complaints about the study or have a research-related injury, contact insert PI name and phone number.

If you cannot reach the Investigator or wish to speak to someone other than the investigator, contact the insert local IRB contact information.

Agreement for additional procedures and release of tumor samples
When you agree to participate in this study, the study team will determine if the additional blood work or biopsy is needed.

1. **This patient has available tumor for research?**

   Yes **No**

2. **Do you agree to allow your tumor that was already collected to be used for this study?**

   Yes **No** **N/A** **_____Initials of Patient**

3. **This patient is being asked to complete a tumor biopsy?**

   Yes **No**

4. **Do you agree to have a tumor biopsy completed prior to starting (if applicable) on this study?**

   Yes **No** **_____Initials of Patient**

Signature:
By signing this form, you are agreeing to participate in this research study under the conditions described. You have not given up any of your legal rights or released any individual or entity from liability for negligence. You have been given an opportunity to ask questions. You will be given a copy of this consent document.

I agree to participate in this study:

_____	_____	_____
PARTICIPANT SIGNATURE	Printed Name	Date
_____	_____	_____
SIGNATURE OF PERSON OBTAINING CONSENT	Printed Name	Date