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| **Official Title:** | A PHASE I/II STUDY OF BOMEDEMSTAT COMBINED WITH MAINTENANCE IMMUNOTHERAPY FOR PATIENTS WITH NEWLY DIAGNOSED EXTENSIVE STAGE SMALL CELL LUNG CANCER (ES-SCLC) |
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Fred Hutchinson Cancer Center
University of Washington Medical Center

**Consent to take part in a research study:**

# A PHASE I/II STUDY OF BOMEDEMSTAT COMBINED WITH MAINTENANCE IMMUNOTHERAPY FOR PATIENTS WITH NEWLY DIAGNOSED EXTENSIVE STAGE SMALL CELL LUNG CANCER (ES-SCLC)

**Principal Investigator**: Rafael Santana-Davila, MD. University of Washington. Fred Hutchinson Cancer Center. Telephone: 206-606-2190

**Sub-Investigators:** Christina Baik, MD, Keith Eaton, MD, PhD, Joseph Hiatt, MD, PhD, Sylvia Lee, MD, Cristina Merkhofer, MD, Cristina Rodriguez, MD, Nicolas Giustini, MD , Diane Tseng, MD, PhD

## Emergency number (24 hours): 206-598-6190

### Important things to know about this study

You are being asked to participate in this clinical research study because you have Small Cell Lung Cancer (SCLC). We are looking to enroll approximately 34 patients over the duration of this study expected to last 24 months.

Research is not the same as treatment or medical care. The purpose of a research study is to answer scientific questions.

Your participation in this study is voluntary, which means you can choose whether you want to participate. If you decide to participate and later change your mind, you are free to stop participation at any time. This consent form was created to help explain to you the nature of the study and if you choose to participate, it will be used to document your agreement to be part of this study.

Please read the following informed consent form to learn about what will happen if you agree to take part in this research study. This consent form may contain some words that you do not understand. Please ask your study doctor or someone from the study staff to explain any words or information that you do not clearly understand. This consent form will give you detailed information about this study. Please ask the study staff as

many questions as you need before you decide if you want to be in the study. You may also want to take home an unsigned copy of this consent form to discuss this study with friends and family before making your decision.

We do not know if bomedemstat will help you, and it could even make your condition/disease worse. Bomedemstat could cause side effects such as those described below in this form.

You can choose to receive standard methods for your disease instead of participating in this study. We will give you details about the purposes, procedures, risks and possible benefits related to this study. We will explain other choices that you have. We will also give you any other information that you need to make an informed decision about joining this study.

After you are sure that you clearly understand the risks and benefits of taking part in this study, if you choose to take part in the study, you will be asked to sign this consent form. You should not sign this consent form if you have any questions that have not been answered. By signing this consent form, you are confirming that the study has been explained to you, and that you give your permission to be a part of the study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

**Why are we doing this study?**

The purpose of this research is to learn about the safety of an investigational drug called IMG-7289 (also referred to as bomedemstat), and how well it is tolerated. It is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration (FDA).

Imago BioSciences, Inc. is the manufacturer of bomedemstat and is providing the study drug for this clinical research study.

**What research tests, procedures, and treatments are done in this study?**

**Trial Treatments**

- Atezolizumab administered on Day 1 of every cycle
- bomedemstat capsules taken daily
    - Once a day, at the same time of day, at night before bed.
    - On an empty stomach. This means not eating food for 1 hour before taking your bomedemstat and for 30 minutes after.
    - By swallowing the capsules whole (do not chew or break them), with a glass of water.
    - You may drink clear liquids at any time before and after taking it.

If you join this study, we would do the following tests and procedures:

**Screening Period**

The following assessments will be performed up to 28 days prior to start of study treatment:

- Request for Archival tissue (tissue from a previous biopsy) if available. You may still participate if you do not have any remaining tissue from a previous biopsy.
- Full Physical Examination
- Vital Signs and Weight
- Determine your performance status (ECOG)
- Pregnancy test for females of childbearing age (within 72 hours of starting therapy)
- A small amount of your blood (between 2-3 tablespoons) will be taken within 10 days of starting therapy
- Tumor imaging (MRI/CT scan)

**Treatment Period**

The following assessments will be performed on day 1 (+/- 3 days) of each treatment cycle and must be performed no more than 24 hours prior to treatment unless otherwise specified. The only exception is for the screening period labs which will serve as baseline assessments and can be performed up to 3 weeks prior or as otherwise specified.

**Day 1 of each new cycle**

- Adverse event review
- Physical examination
- Vital signs and weight
- Performance status
- A small amount of your blood (between 2-3 tablespoons) will be taken
- Tumor Assessments (CT scan done every 8 weeks)

**Day 8 and Day 15 of each new cycle**

- A small amount of your blood (between 2-3 tablespoons) will be taken

**End of Treatment**

The End of Treatment Visit should be conducted at the time of permanent study treatment discontinuation, or within 7 days thereafter.

- Adverse event review
- Physical examination
- Vital signs and weight
- Performance status
- A small amount of your blood (between 2-3 tablespoons) will be taken

**Post-Treatment Visits**

**Safety Follow-Up Visit**

The Safety Follow-Up Visit should be conducted approximately 30 days after the last dose of trial treatment or before the initiation of a new anti-cancer treatment, whichever comes first.

**Follow-up Visits**

Subjects who discontinue trial treatment for a reason other than disease progression will move into the Follow-Up Phase and should be assessed every 8 weeks to monitor your disease status.

**Survival Follow-up**

Once you experience confirmed disease progression or start a new anti-cancer therapy, you will move into the survival follow-up phase and will be contacted by telephone every 12 weeks to assess for survival status until death, withdrawal of consent, or the end of the study, whichever occurs first.

**How long will I be in this study?**

The study is expected to last for 24 months. You will remain in the study as long as you continue to benefit without your disease getting worse (disease progression) or a reaction to the treatment (toxicity)

**Can I stop being in this study?**

- You do not have to join this study. You are free to say “yes” or “no”.
- If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.
- During the study, we might learn new information that you need to know. For example, some information may affect your health or well-being. Other information might make you change your mind about being in this study. If we learn these kinds of information, we will tell you.
- If you join this study, you will not have to stay in it. You could stop at any time (even before you start). Your regular medical care would not change. You would have no penalty for stopping, but it would be better not to join the study if you think that you would change your mind later.

**What are the possible side effects or risks?**

**Possible risks associated with bomedemstat**

Common side effects reported and decided by study doctors to have been possibly, probably, or definitely related to bomedemstat include:

- Low platelet count (47%)
- Nausea (35%)
- Diarrhea (32%)
- Altered taste (25%)
- Low red blood cell level (22%)
- Vomiting (21%)
- Fatigue (15%)

Rare but serious side effects decided by study doctors to have been possibly or probably related to bomedemstat that resulted in hospitalization have been reported.:

- Fever with low white blood cell count (febrile neutropenia; 7%)
- Gastrointestinal (GI) bleeding (2%)
- Low platelet count or worsened low platelet count (2%)
- Bruising (1%)
- Irregular heart rhythm (1%)
- Bleeding in the lungs (1%)
- Worsening lung function (1%)
- Painful spleen (1%)
- Differentiation syndrome (severe headache, sudden fever, difficulty breathing, sudden weight gain; 1%)
- Heart block (1%)

- Constipation (1%)
- Heart failure (1%)
- Fungal infection in the chest (1%)
- Illness with fever (1%)
- Headache (1%)
- Rectal bleeding (1%)

The event below (respiratory failure), which occurred in another study, resulted in the death of a patient. It was determined by the study doctor to have been possibly related to taking bomedemstat. The manufacturer of the drug in consultation with the study medical monitor and members of the study safety committee, concluded that an infection was more likely the cause of the respiratory failure, and decided this event was not related to bomedemstat.

- Respiratory Failure (1%)

Additional side effects have been reported by participants; however, these side effects are not included as they either occurred in less than 15% of participants or were decided by the study doctors to have been unrelated to bomedemstat.

A decrease in the number of various blood cells including platelets (help your blood to clot), white blood cells (help fight infection) and red blood cells (carry oxygen to your body). are side effects of how bomedemstat works. If your platelets and red blood cells become too low, you can be given more by a transfusion. If your white blood cells become too low, your doctor will consider medicines that can help raise them.

**Possible risks associated with Atezolizumab**

Atezolizumab is part of standard treatment for many patients with your disease. However, like any medication, atezolizumab can have side effects.

Atezolizumab is designed to increase the number of immune system cells in your body that can fight cancer. These cells may cause inflammation within the tumor, as well as in normal tissue. Therefore, by receiving atezolizumab, you may develop a condition where there is inflammation against a part of your own body (an autoimmune condition). The side effects associated with atezolizumab are listed below. There may be side effects that are not known at this time.

**Very common** (occurs in more than 10% of subjects)

- Fatigue
- Joint pain (arthralgia)
- Lack of energy (asthenia)
- Decreased appetite
- Diarrhea
- Urinary tract infection
- Shortness of breath (dyspnea) Cough
- Itching of the skin
- Nausea
- Fever
- Rash
- Vomiting
- Muscle and bone pain (myalgia, musculoskeletal pain and bone pain)

**Common** (occurs in 1%-10% of subjects)

- Chills
- Difficulty swallowing (dysphagia)
- Increase in liver enzymes, which may indicate inflammation of the liver
- Allergic reaction or intolerance to medication (hypersensitivity)
- Decreased level of potassium in blood (hypokalemia)
- Inflammation of the intestines (colitis)
- Decreased oxygen supply in body resulting in shortness of breath (hypoxia)
- Flu-like symptoms
- Infusion-related reaction
- Inflammation of the lungs (pneumonitis)
- Low platelet count in the blood, which may make you more likely to bruise or bleed (thrombocytopenia)
- Decreased level of sodium in blood (hyponatremia)
- Low blood pressure (hypotension)
- Underactive thyroid gland (hypothyroidism)
- Nasal congestion
- Stomach area pain (abdominal pain)

- Inflammation of the liver (hepatitis)

**Less common but important** (occurs in less than 1% of subjects)

- Decreased production of hormones by the adrenal glands (adrenal insufficiency)
- Diabetes
- Overactive thyroid gland (hyperthyroidism)
- Inflammation of the brain and membrane surrounding the brain and spinal cord (meningoencephalitis)
- Inflammation of the pituitary gland (hypophysitis)
- Inflammation of the heart muscle (myocarditis)
- Inflammation of the kidneys (nephritis)
  Nerve damage that may cause muscle weakness and/or paralysis (Guillain-Barré syndrome)
- Nerve damage resulting in muscle weakness (myasthenic syndrome/myasthenia gravis)
- Inflammation of the pancreas (pancreatitis)
- Increase in pancreatic enzymes, which may indicate inflammation of the pancreas (increase in amylase and lipase)
- Severe high levels of sugar and acids in the blood or urine (diabetic ketoacidosis)
  Inflammation or damage of the muscles (myositis)

Among the side effects known to be associated with atezolizumab, your study doctors would like you to pay more attention to the following:

- Inflammation of the intestines (colitis); symptoms may include diarrhea, blood in stool, and pain in stomach area
- Inflammation of the thyroid glands (hypothyroidism, hyperthyroidism); symptoms may include headaches, fatigue, weight loss, weight gain, change in mood, hair loss, and constipation
- Inflammation of the adrenal glands (adrenal insufficiency); symptoms may include dizziness, irritability, fainting, low blood pressure, skin darkening, and craving of salty foods
- Inflammation of the pituitary gland (hypophysitis); symptoms may include fatigue and headaches that will not go away, increased thirst, increased urination, and changes in vision. Side effects that may occur at the same time include hypothyroidism and adrenal insufficiency (see above for details).

- Inflammation of the liver (hepatitis); symptoms may include yellowing of skin, pain in stomach area, nausea, vomiting, itching, fatigue, bleeding or bruising under the skin, and dark urine
- Inflammation of the brain and membrane surrounding the brain and spinal cord (meningoencephalitis); symptoms may include neck stiffness, headache, fever, chills, vomiting, seizure, irritability, and eye sensitivity to light
- Nerve damage resulting in muscle weakness (myasthenic syndrome/myasthenia gravis); symptoms may include weakness in the arm and leg muscles, double vision, and difficulties with speech and chewing
- Nerve damage that may cause muscle weakness and/or paralysis (Guillain-Barré syndrome); symptoms may include tingling in fingers and toes, fatigue, and difficulty walking
- Inflammation of the lungs (pneumonitis); symptoms may include new or worsening cough, shortness of breath, and chest pain
- Inflammation of the heart muscle (myocarditis); symptoms may include shortness of breath, decreased exercise tolerance, fatigue, chest pain, swelling of the ankles or legs, irregular heartbeat, and fainting
- Reactions associated with infusion (events occurring during or within 1 day of infusion); symptoms may include fever, chills, shortness of breath, and sudden reddening of the face, neck, or chest
- Inflammation of the pancreas (pancreatitis); symptoms may include abdominal pain, nausea, vomiting, and fever
- Condition of high levels of sugar in the blood (diabetes mellitus); symptoms may include increased thirst, increased hunger, frequent urination, irritability, and fatigue
- Inflammation of the kidneys (nephritis); symptoms may include changes in urine output and color, pain in pelvis, and swelling of the body and may lead to failure of the kidneys
- Inflammation or damage of the muscles (myositis, myopathies including rhabdomyolysis); symptoms may include muscle pain and weakness, urine with a dark brown or reddish color, nausea, and vomiting

**Allergic Reactions**

Allergic reactions may occur with atezolizumab and typically occur while it is being given into your vein or shortly after it has been given. Symptoms could include nausea, vomiting, skin reactions (hives or rash), difficulty breathing, or low blood pressure. These reactions could be mild or severe and might lead to death or permanent disability. If you experience any of these symptoms, your study doctor will interrupt, or even stop, the delivery of atezolizumab into your vein. Your study doctor may also give you some drugs to treat these symptoms.

**Other Possible Risks**

**Side Effects and Risks of Drawing Blood**

During this study, blood will be drawn to perform tests that allow your study doctors to see how you are doing. Blood samples are obtained by inserting a needle into a vein. Drawing blood may cause pain where the needle is inserted, and there is a small risk of bruising, clotting, or, rarely, infection at the place where the needle is inserted. Some people experience dizziness, upset stomach, or fainting when their blood is drawn.

**Radiation risks**

**Magnetic Resonance Imaging (MRI)**

MRI scans use strong magnetic fields and radio waves to produce an image of the inside of the body. There are no known harmful effects from the strong magnetic field used in MRI scans. However, the magnet is so powerful that it can affect any unsecured metal objects, which can be pulled towards the magnet. The magnet may affect pacemakers, artificial limbs, and other medical devices or implants that contain metal. You should discuss any devices in your body with the study staff. You may feel some discomfort or anxiety when lying inside of the scanner. If you cannot have an MRI, you will have a CT.

**Computerized Tomography (CT-scan)**

A CT scan is a specialized x-ray test that takes images of the body. When a CT scan is performed, you will be exposed to radiation. Some of the tests that you will have in this

research study will expose you to radiation. Everyone receives a small amount of radiation every day called “background radiation”. This radiation is natural and comes from space, air, water, soil, and the food you eat. Each year you are exposed to about 3 milliSieverts (mSv) of this background radiation. A milliSievert is a unit of radiation dose.

For comparison, the estimated radiation dose from each CT scan performed in this the study is listed below:

- CT-chest: 7mSv
- CT-abdomen: 8 mSv
- CT-pelvis: 6 mSv
- CT-head: 2 mSv
- CT-neck: 3 mSv

The risk to your health from this level of radiation exposure is too low to be detectable and may be nonexistent.

**Reproductive risks**

The effects of the combination of bomedemstat and atezolizumab on an unborn child or newborn baby are not known. Because of this, it is important that study participants are not pregnant or breast-feeding and do not become pregnant during the study. You must not participate in the study if you are pregnant or trying to become pregnant, or breast-feeding. If you are female and can have children, you will have a pregnancy test before starting study treatment. If you are male, you should not father a child or donate sperm for at least 1 month after the last dose of study medication. Both male and female participants must use effective contraception during the course of the study and for a period of 1 month after completion of the study. Your study doctor will discuss methods of effective contraception with you.

**For female participants** - if you do become pregnant while participating in the study, you should tell the study doctor immediately. Your study doctor will withdraw you from the study and advise on further medical attention should this be necessary. You must not continue in the study if you become pregnant. We will ask you to sign a separate consent and plan on following you during your pregnancy until outcome.

**For male participants** - you should tell the study doctor if you father a child while participating in the study. We will ask your partner to sign a separate consent and plan on following them during their pregnancy until outcome.

Treatment with bomedemstat and atezolizumab is not chemotherapy and is unlikely to cause temporary or permanent sterility. Please discuss with your study doctor any concerns about future fertility.

**What are the benefits?**

You may or may not receive any benefit from this investigational study. It is possible that you may get better, stay the same, or get worse.
Your participation in this study may help future patients with this disease.

**Would you have extra costs if you join this study?**

If you join this study, you or your insurance company would have to pay for the costs of standard treatment and procedures related to your disease.

You would not be billed for:

- bomedemstat, the investigational drug. The drug manufacturer of this study, Imago BioSciences, Inc., will provide bomedemstat to you free of charge.

**Will I be paid for my participation in this study?**

There is no payment for being in this study.

**What are my Other Treatment Options?**

- Instead of taking part in this investigational study, you may choose to receive standard treatment with other drugs and/or therapies that may be used to treat advanced cancers.
- You could also participate in a research study or choose no treatment at all. The risks and benefits of these other treatments will be explained to you by your doctor. Your doctor will answer any questions you have about these other treatments.
- If you decide that you don't want any more active treatment, one of your options is called "comfort care." Comfort care includes pain medication and other support. It aims to maintain your comfort and dignity rather than cure disease. Usually this care can be provided at home. If you think you might prefer comfort care, please discuss this with your family, friends, and your doctor.

**Voluntary Participation and Withdrawal**

Taking part in this investigational study is voluntary. You do not have to participate in this investigational study. You can agree to be in this study now and change your mind later. Your decision will not affect your regular care or the benefits to which you are otherwise entitled.

You can decide to stop at any time. Tell your doctor if you are thinking about stopping or decide to stop. Your doctor will tell you how to stop safely.

It is important to tell your doctor if you are thinking about discontinuing treatment on this investigational study. This is so you and your doctor can discuss what follow-up care, testing, and other treatments could be most helpful for you.

If you participate in this study, we will collect your information. If you withdraw from the study, previously collected information would remain in our databases and may be included in the future analyses.

Your doctor or the drug manufacturer may take you off this study at any time without your consent. There are other reasons that you may be removed from the study including:

- They think it is in your best interest not to continue to be treated on this study,
- You are not able or willing to comply with the study,
- The drug manufacturer stops providing the investigational drug, or
- For any other reason.

**Rejoining the Study after Treatment for Central Nervous System Metastases**

If you participate in the study, your doctors will monitor your cancer using CT and/or MRI scans at regular intervals. If there is cancer growing in the brain and/or spinal cord (the central nervous system or CNS), one of two scenarios could occur:

1. Your doctors determine that it is in your best interest <u>not</u> to receive further treatment in this study. They may recommend other forms of treatment such as radiation or other medications outside of this study. This is expected to be the most common scenario.

2. Your doctors determine that it <u>may be</u> in your best interest to receive further treatment in this study <u>after</u> you receive treatment for the cancer in the CNS. Treatment for cancer in the CNS could consist of radiation or other treatments, and does not have to be administered by doctors that are affiliated with the study or

with the Fred Hutchinson Cancer Center. You could receive this treatment at a qualified medical facility that is convenient to you. Study treatment would be paused while you receive treatment for the cancer in the CNS. Once that treatment is completed, the study doctors will reassess whether resuming study treatment might be in your best interest. If they determine that resuming study treatment could be in your best interest, they will discuss with you the risks and benefits of resuming study treatment versus pursuing other treatment options (see Other Treatment Options section above). As at any other point in the study, you do not have to agree to continue participating in the study. This is expected to be the less common scenario.

**Confidentiality and Protecting Privacy of Personal Information**

The following information explains how your medical and health records may be used and disclosed. We will make every effort to keep your records private.

If you consent to this study, information about your participation would be made part of your permanent medical record. This information would include a copy of this consent form. If an insurance company or employer or anyone else were authorized to see your medical record, they would see a copy of this consent form

If you join this study, some people or organizations might need to look at your medical records and research records for quality assurance or data analysis.

They include:

- Imago BioSciences (the drug manufacturer) and their agents
- Physicians and staff involved with this treatment.
    - Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Center IRB. An IRB is a group that reviews the study to protect the rights and welfare of research participants.

- Fred Hutchinson Cancer Center, University of Washington.
- Office for Human Research Protections, Food and Drug Administration, NIH/NCI and other regulatory agencies as required.

The results of the study may be published in a medical book or journal or presented at meetings for educational purposes. If the results of this study are published, you will not be personally identified, and your identity will not be disclosed. During that time, results will be kept confidential to the extent permitted by law. Your participation in this study will be noted in your UW medical record.

This research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate helps protect the confidentiality of information about people who join this study. If you join the study, the Certificate means that generally we would not have to give out identifying information about you even if we were asked to by a court of law. We would use the Certificate to resist any demands for identifying information.

We could not use the Certificate to withhold research information if you give written consent to give it to an insurer, employer, or other person.

This protection has some limits. We would voluntarily provide the information:

- To a member of the federal government who needs it in order to audit or evaluate the research.
- To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly.
- To the federal Food and Drug Administration (FDA), if required by the FDA.
- To someone who is accused of a crime, if he or she believes that our research records could be used for defense.
- To authorities, if we learn of child abuse, elder abuse, or if participants might harm themselves or others.

**What if you get sick or hurt after you join this study?**

For a life-threatening problem, call 911 right away or seek help immediately. Contact your study doctor when the medical emergency is over or as soon as you can.

If you are injured or hurt as a result of taking part in this investigational study and need medical treatment, please tell your doctor and medical care will be provided to you. The costs of medical treatment will be billed to you or your insurance company. Your insurance company may not be willing to pay for the investigational study related injury. If you have no insurance, you will be responsible for any costs. If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are participating in an investigational study.

To help avoid injury, it is very important to follow all directions.

We will bill you and your insurer for treatment of problems that result from your disease or standard clinical care.

No money has been set aside to pay for things like lost wages, lost time, or pain. However, you do not waive any rights by signing this consent form. The above statements do not limit your legal rights. You still have the right to make a claim through the legal system even if you sign this consent form. By signing this consent form, you have not given up any of your legal rights to seek compensation.

**Will my information and/or tissue samples ever be use for future research?**

If you did have left over tissue, and provided to us, we might remove all identifiers and codes from the sample. We could then use or share them with other researchers for

future research. If you do not want your anonymous information or tissue samples used for other projects, you should indicate that on this consent.

If you agree and we do share your information or tissue with others, we would not be able to stop the future research, even if you asked later. There will be no way to link the information or tissue samples back to you. We will not contact you or otherwise inform you before we share your information or tissue for future research.

Future genetic research databases

Several genetic databases are available to help researchers understand different diseases. These databases contain DNA code and medical information from participants who have various diseases.

As part of this study, we would like to release DNA code and information about your medical condition into a genetic database in order to help future research. The genetic database would not contain names, addresses, or other information that could be used to identify you.

The DNA code in a genetic database cannot be used by itself to identify any specific person. A researcher who already has DNA code about you could use information from a genetic database to learn more about you. Once we release information to a genetic database, we no longer have any control over the use of this information.

**Your rights and Your responsibilities**

- You do not have to join this study. You are free to say “yes” or “no”.
- If you get sick or hurt in this study., you do not lose any of your legal rights to seek payment by signing this form.

- During the study, we might learn new information that you need to know. For example, some information may affect your health or well-being. Other information might make you change your mind about being in this study. If we learn these kinds of information, we would tell you.

- If you join this study, you would not have to stay in it. You could stop at any time (even before you start). Your regular medical care would not change. You would have no penalty for stopping, but it would be better not to join the study if you think that you would change your mind later.

- If you decide to drop out, we would want you to tell the treating doctor. The doctor could tell you about the effects of stopping bomedemstat. You and the doctor could talk about the follow-up care and testing that would help the most.

**How is my genetic information protected?**

A federal law called the Genetic Information Nondiscrimination Act (GINA) helps protect genetic information about people who join research studies.

GINA restricts access to genetic information so that it cannot be used for health insurance coverage decisions. GINA prevents health insurance companies or group health plans from:

- Asking for genetic information obtained in research studies, or
- Using genetic information when making decisions regarding your eligibility or premiums

GINA does not help or protect against genetic discrimination by companies that sell life, disability or long-term care insurance.

**For more information**

If you have questions or concerns about this study, you could talk to your doctor anytime. Other people you could talk to are listed below.

| **If you have questions about:** | **Call:** |
|---|---|
| This study (including complaints and requests for information) | Dr. Rafael Santana-Davila (206) 606-2190 |
| If you get sick or hurt in this study | Dr. Rafael Santana-Davila (206) 606-2190<br>Rebecca Wood Research Mgr. (206) 606-6970 |
| Your rights as a research participant | 206-667-5900 or email irodirector@fredhutch.org (Director of Institutional Review Office, Fred Hutchinson Cancer Center)<br>206-543-0098 (Human Subjects Division, University of Washington) |
| Your bills and health insurance coverage | The financial services department at Fred Hutchinson Cancer Center at (206) 606-6232 |

**Emergency number (24 hours): 206-598-6190**

Do you agree to donate your archival tissue if available to study cancer?

(Circle One)

**YES NO**

Is it OK if we send your genetic information to one or more databases for future research?

(Circle One)

**YES NO**

**Signature**

Please sign below if you:

- have read this form (or had it read to you);
- had the opportunity to ask any questions you have;
- had the opportunity to discuss the research with the person obtaining consent. and
- agree to participate in this study.

_____

Subject Name (printed)

_____

Signature of Subject Date

I have discussed the research study, including procedures and risks, with the person signing above. A copy of the signed consent form will be given to the participant.

_____

Printed Name of Person Conducting Informed Consent Discussion

_____

Signature of Person Conducting Consent Discussion Date

If you were a witness for a participant who was not able to read this written consent form, sign below to indicate (1) you were present at the consent discussion in person, (2) you witnessed the verbal presentation of the written consent form, and (3) the participant had the opportunity to ask questions and agreed to take part in the study.

Impartial Witness:

_____

Printed Name

_____

Signature Date

Current version date: 20220807

Previous version date: 20220308

Copies to: Participant and Medical Record