NCT# 01554371

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

CC#11996: Study Title: A Phase Ib/II study of eribulin in combination with cyclophosphamide in patients with solid tumor malignancies

This is a clinical trial, a type of research study. Your study doctor, Dr. Hope Rugo and her associates from the UCSF Department of Medicine, will explain the clinical trial to you.

Clinical trials include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you have cancer that has spread to other parts of your body and your doctor has recommended treatment with chemotherapy.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to test the safety of eribulin (Halaven™) and cyclophosphamide (Cytoxan®) given together at different doses. We want to find out what effects, good and/or bad, these drugs have on you and your cancer.

Eribulin is a drug that has been approved by the U.S. Food and Drug Administration (FDA) for breast cancer that has spread to other parts of the body. Cyclophosphamide has been approved for different types of cancers (including breast cancer). However, the combination of eribulin and cyclophosphamide is considered experimental; that means this combination has not been approved by the FDA.

The funding for this study is provided by Eisai Inc., the maker of eribulin.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Up to 18 patients will participate in this study in the first portion of this study (Phase Ib). Approximately 40 patients will participate in the phase II portion. A combined total of 58 subjects will be enrolled at UCSF in both phases of the study.

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

Each study visit may last between 3 to 6 hours depending on the particular procedures. The first day of the study drug dose will last over 8 hours due to the pharmacokinetics (PK) blood samplings.

Before you begin the main part of the study...

You will need to have the following exams, tests or procedures to find out if you can be in the main part of 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.

- Medical history and physical exam
- Review of any medications you are currently taking or have taken within the last 30 days
- Radiographic studies which may include a CT scan (to monitor the cancer in your organs), PET scan, or bone scan (if your cancer has spread to your bones)
- Other radiology tests may need to be done depending on your type of cancer
- Electrocardiogram (EKG): Done to monitor how your heart is working
- Laboratory/blood tests: Routine tests done to see if your kidney, liver, and other organs are working well
- Pregnancy test (if you are a female of childbearing age)
- Research blood tests

During the main part of the study...

If the exams, tests and procedures show that you can be in the main part of the study, and you choose to take part, then you will need to have the tests and procedures described below.

Study drug administration:

You will receive treatment with eribulin and cyclophosphamide as described below. The same treatment will be repeated every 3 weeks (21-days). This 3-week period is called a treatment cycle.

Cyclophosphamide is injected into a vein on the first day (Day 1) of each cycle. The injection will take approximately 60-120 minutes. The exact dose of cyclophosphamide you receive will also be calculated based on your weight and height.

You will also receive eribulin. Eribulin is injected into a vein on Day 1 and Day 8 of each cycle. The injection will take approximately 2-5 minutes. The exact dose of eribulin you receive will also be calculated based on your weight and height.

At the beginning of the study (the Phase Ib portion), the first group of patients will be treated with a lower dose of study drug. If this low dose causes no or minimal side effects, new patients enrolled in the study will be given a slightly higher dose. Additional patients will be given higher doses until we have determined the highest dose that can be given without severe side effects; patients in the second part of the study (Phase II portion) will receive this highest dose.

Neither you nor your doctor can choose the group you will be in. You can ask your doctor what group you will be in and what dose of study drug you will be receiving.

Procedures that are part of regular cancer care:

- Physical exam (once per cycle)
- Performance score: You will be asked questions about your daily activities to evaluate your level of daily function.
- Laboratory/blood tests (twice per cycle in the Phase Ib portion, and twice per cycle in Cycle 1 and Cycle 2, then once per cycle in Cycle 3 and beyond in the Phase II portion)
- CT, PET/CT, bone scan, and/or other radiology tests (every 6 weeks in the Phase Ib portion, and every 9 weeks in the Phase II portion)

Procedures that are for research purposes only:

- EKG (once; cycle 1)
- Blood samples for Pharmacokinetic (PK) tests (Cycle 1): PK blood samples will be collected over an 8-hour period at the following time points: before you receive the study drug infusion (pre-dose), at the end of your study drug infusion, and then 15 minutes, 30 minutes, 1, 2, 3, 4, 6 and 8 hours following your infusion.
- Blood sample for Pharmacogenomic tests (once; before your first treatment)
- Blood samples for measuring circulating tumor cells (CTCs) (Cycle 1 and possibly Cycle 2, depending on the results from your Cycle 1 test)
- Archival tumor tissue (this is optional – permission is given at the end of this form)
- Neuropathy assessment (before your first treatment, then once per cycle beginning with cycle 2)
- Neuropathy questionnaire (before your first treatment, then once per cycle beginning with cycle 2)
- Quality of Life (QOL) questionnaire (before your first treatment, then at 6 weeks, 3 months, 12 months, 18 months, 24 months, and/or at study termination)

When you are finished receiving eribulin and cyclophosphamide...

If you decide to discontinue your participation in the study or if your study doctor decides you should not continue in the study, the following procedures will be carried out within 30 days after you receive your last dose of study drug:

- Physical exam
- Performance test
- Laboratory/blood tests
- Blood sample for research tests
- Neuropathy assessment

- Review of any medications you are taking
- Review of any side effects you may be experiencing
- Neuropathy questionnaire
- Quality of Live (QOL) questionnaire
- Radiographic studies which may include a CT scan (to monitor the cancer in your organs), PET/CT scan or bone scan (if your cancer has spread to your bones)

Study location: Study procedures will be done at UCSF, Mt. Zion Campus, [redacted].

DESCRIPTION OF PROCEDURES

Blood drawing (venipuncture):
This involves inserting a needle into a vein in your arm. Each blood sample will be approximately 2 teaspoons.

Bone Scan:
A bone scan is a test that makes detailed images of your bones and any tumors on them. Before the bone scan a small amount of radioactive substance is injected into your vein. About 3 hours later you will lay on a table under a machine which will make an image of your bones. The test itself will take about 1 hour, but the whole process takes up to 4 hours.

CT or PET/CT scan:
You will have a computerized tomography (CT) scan or positron emission tomography/CT (PET/CT) scan to check the status of your tumor. These scans use special x-ray equipment to make detailed pictures of body tissues and organs.

You may first be injected with contrast material (iodine dye and/or radioactive substance). This contrast material makes your tissues and organs more visible in the pictures. You will be asked to rest for about 30 minutes while the contrast material circulates throughout your body.

For the scan, you will need to lie still on a table inside a large doughnut-shaped machine. The table will move and the machine will make clicking and whirring noises as the pictures are taken. Each scan will take between 15 minutes to an hour.

EKG (electrocardiogram)**:**
An EKG records the natural electrical activity of your heart. You will lie down, and wires or "leads" will be attached to your chest with an adhesive. You will be asked to lie still while the machine prints out an electrical "picture" of your heart activity. The EKG takes about 15 minutes.

Neuropathy assessment:
Exam by the study doctor to check for any numbness or tingling in the toes and fingers

Questionnaires (Neuropathy and Quality of Life (QOL)):
Because the study drug eribulin may potentially cause nerve damage, the study doctors will assess you for any nervous system changes throughout your participation in the study. This will be done by filling out these two questionnaires. These are standard questionnaires that are commonly used by health care professionals.

Blood samples for research:
This includes Pharmacogenomic (PG), Pharmacokinetic (PK), and circulating tumor cell (CTC) tests. These tests are done to look for the presence or absence of certain genetic material (DNA or RNA) and proteins in your blood. This genetic material and protein are referred to as "biomarkers". These biomarkers may come from healthy cells or from cancer cells circulating in your blood.

Studying these biomarkers may help us understand why different people respond differently to the study drugs (for example how it is stored, broken down, and excreted from the body, or why some people respond favorably to the drugs and some don't).

No more than 2 tablespoons will be taken at any one time.

Archival Tumor Tissue samples for research (optional):
This tissue will be taken from a biopsy or surgery that was performed to diagnose your cancer. You do not need to undergo any extra procedure to donate this sample. Only extra tissue (tissue that is not needed to plan your care and which would normally be discarded) will be used to perform these research tests.

Research tests performed on this tissue will involve looking for biomarkers (similar as for the blood samples above)

Blood sample for future genetic research (optional):
You may be asked to donate a blood sample (1-2 tablespoons) before the start of the treatment for future genetic testing. This sample is optional and will be discussed in greater detail at the end of this consent.

WHAT ARE MY RESPONSIBILITIES WHILE I AM IN THE STUDY?

It is important that you follow the instructions of the study doctor and study team. It is important that you come to all of your scheduled study visits. It is also important that you follow the schedule when you take the study drug.

It is important that during the study, you tell the study doctor and/or the study team all changes in how you feel. You need to tell them even if you do not believe these changes are related to the study. This may include mental or emotional changes. You will be checked during the study for side effects. You will also be checked for other injuries or illnesses that may happen while you are in the study.

Before taking any medicines besides the study drug, you must first ask the study doctor. These medicines may be ones that are ordered by a doctor. They may also be drugs like allergy medicines, cough and cold medicines and pain relievers, or they may be vitamins, herbs and minerals. The use of any investigational or antitumor therapies (other than eribulin and cyclophosphamide given as part of the study) is prohibited.

Only you, the study subject, can take the study drug.

HOW LONG WILL I BE IN THE STUDY?

You may continue participating in the study as long as the doctor feels you are benefitting from the treatment, or until you no longer wish to participate.

Your study doctor or the sponsor may also decide to end your participation at any time without your approval if:

- The study is stopped by the Sponsor or the FDA for any reason
- You fail to follow instructions given by the study doctor
- There is a change in your medical condition
- The study doctor believes it is best for you to no longer be in the study

For your safety, you will be asked to return to this office for a follow-up visit if you leave the study. Your visit may include tests like physical exams and blood draws. Your visit may also include questions about your medical condition. It is important that you tell the study staff any problems or changes in the way you felt while you were in the study.

The researchers will continue to monitor your health for up to 10 years after you complete the final study visit. This will involve reviewing your medical record periodically to see how you are doing.

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 your participation safely.

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

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

WHAT SIDE EFFECTS OR RISKS CAN I EXPECT FROM BEING IN THE STUDY?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the study drugs. In some cases, side effects can be serious, long lasting, or may never go away. There is also a risk of death.

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

Risks of eribulin:

Common side effects:

- Decreased white blood cells (may increase chance of infection)
- Decreased red blood cells (may cause weakness and tiredness)
- Fatigue
- Hair loss
- Peripheral neuropathy (a form of damage to the nerves supplying the hands and feet, which leads to numbness or the feeling of "pins and needles" and/or impairment of muscle strength in the hands and feet)
- Nausea
- Constipation

Less common side effects:

- Eyes watering
- Upset Stomach/abdominal pain
- Inflammation or ulcers in the mouth (stomatitis)
- Dry mouth
- Fluid retention
- Upper respiratory tract infection
- Low potassium in the blood (can cause constipation, weakness, and abnormal heart rhythms)
- Muscle spasms, muscular weakness
- Change in taste
- Dizziness

- Insomnia
- Depression
- Rash
- Liver function test changes

Risks of Cyclophosphamide:

- Decrease in bone marrow function (resulting in lower level of blood cells)
- Low levels of all blood cells (white blood cells, red blood cells, platelets)
- Liver function test changes
- Inability to have children
- Rash
- Skin pigmentation changes
- Nail changes
- Stevens-Johnson syndrome (severe reaction that includes a painful rash that spreads and blisters, causing the top layer of skin to die and shed)
- Congestive heart failure
- Infusion-related symptoms such as fever, chills, rigors, headache
- Abdominal pain
- Nausea
- Vomiting
- Diarrhea
- Inflammation or ulcers in the mouth and digestive tract (mucositis)
- Hair loss
- Anorexia
- Pain
- Irritation of the bladder, which causes pain and can result in blood in the urine
- Scarring of the bladder
- Inflammation and pain in the urinary tract
- Kidney damage
- Stomach flu
- Inflammation and scarring of the lungs

- Jaundice
- Infections
- Secondary cancer
- Anaphylaxis (a severe, whole-body allergic reaction, which may require immediate medical attention)
- SIADH (Excessive water retention that may cause electrolytes in your blood to fall to low levels)
- General feeling of being sick (Malaise)
- Lack of energy or strength

Additional information on cyclophosphamide (Cytoxan®) may be found in the approved package insert.

OTHER RISKS

Medications:
Before taking any over the counter medicines, herbal products, vitamins, food supplements, or any other types of special products while participating in this study, please discuss this with the study doctor who will tell you whether it is appropriate to start or continue taking these medicines. You should also talk to the study doctor before taking any medicines other doctors may have prescribed for you. This is to ensure that there are no harmful interactions between the study drug and any other medicines you are taking. Your study doctor may need to change or discontinue these for the duration of the study.

Blood drawing (venipuncture) risks:
Drawing blood may cause temporary discomfort from the needle stick, bruising, and infection.

Radiation (x-ray) risks:
The amount of radiation you will be exposed to is relatively small. Such doses of radiation may be potentially harmful, but the risks are so small that they are difficult to measure. If you have already had many x-rays, you should discuss this with the researchers before agreeing to be in the study.

CT and PET/CT scan risks:
CT scans involve the risks of radiation (see above). In addition, if contrast material is used, there is a slight risk of developing an allergic reaction, from mild (itching, rash) to severe (difficulty breathing, shock, or rarely, death). The contrast material may also cause kidney problems, especially if you are dehydrated or have poor kidney function. The study doctors will ask you about any allergies or related conditions before the procedure. If you have any of these problems, you may not be allowed to have a CT scan.

Having a CT scan may mean some added discomfort for you. In particular, you may be bothered by feelings of claustrophobia when placed inside the CT scanner, or by lying in one position for a long time. If contrast material is used, you may feel discomfort when it is injected. You may feel warm and flushed and get a metallic taste in your mouth. Rarely, the contrast material may cause nausea, vomiting or a headache.

Bone scan risks:
Risks include radiation exposure as well as possible bruising from the injection of contrast. Some subjects may be uncomfortable lying flat.

Pregnancy risks:
The effects of the study drugs (eribulin and cyclophosphamide) on an unborn child are currently unknown. Therefore it is important that you take measures to avoid becoming pregnant while participating in the study. If you are pregnant, breast-feeding, or if you are not planning to take precautions against pregnancy, you are not allowed to take part in this study.

If you are a woman who is not menopausal, a pregnancy test will be performed prior to study start. You should discuss any pregnancy plans with your study doctor before you are registered in this study. Additionally you must agree to use medically acceptable contraception as suggested by your study doctor for the time you are receiving the study drugs.

If it is possible for you to become pregnant, you must agree to use two highly effective forms of birth control - one of which must be a barrier method (for example, use of a spermicide, an intrauterine device (IUD) or oral contraceptive, plus a barrier method such as a condom, diaphragm or cervical cap). Oral contraception must not be used alone.

You and your partner must use adequate birth control from at least the first day of your last normal menstrual period before you take a study drug, and should continue until 30 days after the last dose of study drug.

The only subjects who will be exempt from the birth control requirement are those who are unable to become pregnant:

- Women who had hysterectomy (uterus removed), bilateral oophorectomy (both ovaries removed), bilateral tubal ligation and documentation of the procedure.
- Postmenopausal women in the appropriate age group who had their last period more than 1 year before start of the study treatment.
- If your partner had a vasectomy more than 3 months ago and a follow-up check showed zero sperm count, then you do not need other birth control.

If you are abstinent (no sexual intercourse), you must agree to use an acceptable method of birth control if you become sexually active during the study.

If you become pregnant during the study or think that you might be pregnant, you must notify the study doctor immediately.

Unknown Risks:
The experimental treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

For more information about risks and side effects, ask your study doctor.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Taking part in this study may or may not make your health better. While doctors hope eribulin combined with cyclophosphamide will be more useful against cancer compared to the usual treatment, there is no proof of this. We do know that the information from this study will help doctors learn more about eribulin as a treatment for cancer. This information could help future cancer patients.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

If you choose not to participate in this research study, other procedures or treatments for your cancer could include:

- Surgery to remove tumors
- Radiation to shrink tumors
- Other anticancer therapy (either experimental or not experimental), which may include cyclophosphamide or other chemotherapy.
- Getting no treatment
- Getting comfort care. This type of care could help reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

Depending on your type of cancer, its location and your general condition, all, some, or none of these alternatives may be appropriate.

Another choice available to you is simply to receive supportive care to help manage only the symptoms and pain produced by your cancer. Your study doctor will discuss the other treatments available to you for your cancer.

Please talk to your doctor about your choices before deciding if you will take part in this study.

WILL MY MEDICAL INFORMATION BE KEPT PRIVATE?

We will do our best to make sure that the personal information in your medical record is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The sponsor (Eisai, Inc.), it's affiliated Eisai companies, and it's consultants who are helping to conduct this study
- Government agencies such as the National Cancer Institute (NCI) and the Food and Drug Administration (FDA), involved in keeping research safe for people.
- The University of California

Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. A medical record will be created because of your participation in this study. Your consent form and some of your research test results will be included in this record. Therefore, your other doctors may become aware of your participation. Hospital regulations require that all health care providers treat information in medical records confidentially.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

You and/or your health plan/insurance company will need to pay for some or all of the costs of treating your cancer in this study. Some health plans will not pay these costs for taking part in studies. Check with your health plan/insurance company to find out what they will pay for. Taking part in this study may or may not cost you or your insurance company more than the cost of getting regular cancer treatment.

The study drug eribulin will be provided by the sponsor (Eisai, Inc.) at no cost to you. Cyclophosphamide will be billed to you or your insurance.

Procedures that are done specifically for this study (which are not part of your regular care) will be paid for by the study sponsor. Other procedures, which are also done in this study but are part of your normal care, will be paid for by your or your insurance.

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 TAKING PART IN THIS STUDY?

You will not be paid for taking part in this study.

You may be eligible to be reimbursed for reasonable travel expenses of up to a maximum of $25 related to each study visit. The study doctor or staff can explain the procedures and requirements (such as receipts) for such reimbursement. You will not receive any other money or payments.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

It is important that you tell your study doctor, Hope Rugo, M.D., if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her [redacted]

> **Treatment and Compensation for Injury**: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Committee on Human Research at 415-476-1814.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctor Hope Rugo, M.D., [redacted]

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Office of the Committee on Human Research at 415-476-1814.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of study results. You can search this Web site at any time.

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Please note: *This section of the informed consent form is about additional research studies that are being done with people who are taking part in the main study. You may take part in these additional studies if you want to. You can still be a part of the main study even if you say "no" to taking part in any of these additional studies.*

You can say "yes" or "no" to each of the following studies. Please mark your choice for each study.

1. About Using Archival Tumor Tissue Specimens for Research

As part of this study, research tests will be done on your tumor tissue specimens from the prior biopsy or surgery that was performed to diagnose your cancer. (if you give permission, below).

If there are any leftover tumor tissue specimens after these research tests are done, we would like to keep these specimens for future research. If you agree, these specimens will be kept and may be used in research to learn more about cancer and other diseases. The research that may be done with your specimens is not designed specifically to help you. It might help people who have cancer and other diseases in the future.

A small amount of genetic material (DNA) may be obtained from your specimens to understand what mutations (changes) have developed in the DNA to cause the cancer, as well as help scientists understand why your tumor may or may not respond to the study drugs.

Reports about research done with your tissue will not be given to you or your doctor. These reports will not be put in your health record. The research will not have an effect on your care.

Things to Think About

The choice to let us keep the left over specimens for future research is up to you. No matter what you decide to do, it will not affect your care.

If you decide now that your specimens can be kept for research, you can change your mind at any time. Just contact us and let us know that you do not want us to use your tissue. Then any tissue that remains will no longer be used for research. To do this, please contact your study doctor at the address below:

Hope Rugo, M.D.
University of California San Francisco, [redacted]

In the future, people who do research may need to know more about your health. While the study doctors may give them reports about your health, they will not give them your name, address, phone number, or any other information that will let the researchers know who you are.

Sometimes tissue is used for genetic research (about diseases that are passed on in families). Even if your tissue is used for this kind of research, the results will not be put in your health records.

Your tissue will be used only for research and will not be sold. The research done with your tissue may help to develop new products in the future.

Benefits

The benefits of research using tissue include learning more about what causes cancer and other diseases, how to prevent them, and how to treat them.

Risks

The greatest risk to you is the release of information from your health records. We will do our best to make sure that your personal information will be kept private. The chance that this information will be given to someone else is very small.

Making Your Choice

Please read the sentence below and choose "yes" or "no". No matter what you decide to do, it will not affect your care.

I agree to donate a leftover tumor tissue specimen that was previously collected as part of my clinical care for research tests related to this study.

YES	NO

2. **About Using Blood Sample for Future Research**

As the main part of the study, you are going to have blood samplings before the start of the treatment. We would like to draw extra blood (1-2 tablespoons) for future genetic study when drawing the study blood samplings. The research that may be done with your blood is not designed specifically to help you. It might help people who have cancer and other diseases in the future.

A small amount of genetic material (DNA) may be obtained from your blood and a genome scan (a method to detect anomalies in the sequence of individual people's DNA) will be performed to understand what mutations (changes) have developed in the DNA to cause the cancer, as well as help scientists understand why your tumor may or may not respond to the study drugs.

Reports about research done with your blood will not be given to you or your doctor. These reports will not be put in your health record. The research will not have an effect on your care.

Things to Think About

The choice to let us collect and use your blood for future genetic research is up to you. No matter what you decide to do, it will not affect your care.

If you decide now that your blood sample can be collected and used for research, you can change your mind at any time. Just contact us and let us know that you do not want us to use your blood sample. Then any sample that remains will no longer be used for research. To do this, please contact your study doctor at the address below:

Hope Rugo, M.D.
University of California San Francisco[redacted]

In the future, people who do research may need to know more about your health. While the study doctors may give them reports about your health, they will not give them your name, address, phone number, or any other information that will let the researchers know who you are.

This blood sample will be used for genetic research and the results will not be put in your health records.

Your blood sample will be used only for research and will not be sold. The research done with your blood sample may help to develop new products in the future.

Benefits

The benefits of research using blood sample include learning more about what causes cancer and other diseases, how to prevent them, and how to treat them.

Risks

The greatest risk to you is the release of information from your health records. We will do our best to make sure that your personal information will be kept private. The chance that this information will be given to someone else is very small.

Genetic information that results from this study does not have medical or treatment importance at this time. However, there is a risk that information about taking part in a genetic study may

influence insurance companies and/or employers regarding your health. To further safeguard your privacy, genetic information obtained in this study will not be placed in your medical record.

Taking part in a genetic study may also have a negative impact or unintended consequences on family or other relationships. If you do not share information about taking part in this study, you will reduce this risk. Although your name will not be with the sample, it will have other facts about you such as age, sex, ethnicity and treatment. These facts are important because they will help us learn if the factors that cause cancers to occur or get worse are the same or different based on these facts. Thus it is possible that study finding could one day help people of the same race, ethnicity, or sex as you. However, it is also possible through these kinds of studies that genetic traits might come to be associated with your group.

Making Your Choice

Please read the sentence below and think about your choice. After reading the sentence, put your initials in the "Yes" or "No" box. If you have any questions, please talk to your doctor or nurse, or call our research review board at IRB's phone number.

I agree to allow my blood sample to be used for future genetic research to learn about, prevent, or treat cancer or other diseases.

YES	NO

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CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date	Participant's Signature for Consent
Date	Signature of the Person Obtaining Consent
Date	Witness – Only required if the participant is a non-English speaker

Medications and Foods to Avoid

The following is a list of medications to avoid while you are on this study, including medications which are prohibited and also those permitted if needed, but not recommended.

Before you begin treatment, the study doctor will review all medications you are taking. Make sure you talk with the study doctor before you start or stop taking any medications. This information will be reviewed at each study visit.

In addition to the listed medications you should also avoid eating or drinking juice from Seville oranges (also known as sour or bitter oranges), grapefruit, pomegranate, and starfruit. If you go to any other medical or dental visit, please take this list with you for the doctor's reference.

Generic Name	Brand Names ®	Generic Name	Brand Names ®
Amprenavir	Agenerase	Nevirapine	Viramune
Atazanavir	Reyataz	Nicardipine	
Astemizole		Opioid analgesics	
Barbituates		Oxcarbazepine	Trileptal
Carbamazepine	Tegretol	Pentobarbital	
Cisapride	Propulsid	Phenobarbital	Luminal
Conivaptan		Phenytoin	Dilantin
Delavirdine	Rescriptor	Pimozide	Orap
Fosamprenavir	Lexiva	Posaconazole	Noxafil
Fosphenytoin	Cerebyx	Primidone	
Imatinib		Quinidine	Cardioquin, Quinora
Indinavir	Crixivan	Rifabutin	Mycobutin
Isoniazid		Rifampin	Rifadin, Rimactane
Itraconazole	Sporanox	Rifapentine	
Ketoconazole (oral)			Norvir
Nafcilin			
Nefazodone			
Nelfinavir	Viracept		Ketek