NCT05191472

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

Study Title: CC# 212530: Phase II study of Pembrolizumab in Multiple Myeloma Patients Relapsing After or Refractory to Anti-BCMA CAR-T Therapies

Principal Investigator:	Alfred Chung, MD Assistant Professor University of California San Francisco [redacted] San Francisco, CA 94143 [redacted]

This is a clinical research study. Your study doctor, Alfred Chung, MD, from the UCSF Department of Hematology will explain the study to you.

Research studies include only people who choose to take part. It is your choice whether or not you want to take part in this study. Please take your time to make a decision about participating. You can discuss your decision with your family, friends, and 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 multiple myeloma that either did not respond to or returned following anti-BCMA CAR-T therapy.

Why is this study being done?

The purpose of this study is to test the safety of pembrolizumab and find out what good and/or bad effects it has on patients with multiple myeloma that either did not respond to or returned following anti-BCMA CAR-T therapy.

Pembrolizumab is an immunotherapy drug that works by helping your immune system fight cancer cells. Pembrolizumab is approved by the United States Food and Drug Administration (FDA) for treatment advanced melanoma. The FDA has not approved the use of pembrolizumab for treating multiple myeloma. Therefore, pembrolizumab is being used in this study as an investigational drug.

Participants in this study will receive 200 mg of pembrolizumab every 3 weeks for up to 2 years, until their disease gets worse (progresses), until they cannot tolerate the side effects, or until they make the decision to end their study participation.

Merck, the manufacturer of pembrolizumab, is supplying pembrolizumab at no cost to study participants, and is providing funding to UCSF for this study.

How many people will take part in this study?

About 25 people will take part in this study.

What will happen if I take part in this research study?

Before you begin the main part of the study:

You will need to have the following tests and procedures to find out if you can be in the main part of the study. Some of these tests and 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.

- You will have a physical examination including measurement of your height, weight, and vital signs (temperature, blood pressure, respirations, and heart rate).
- Your medical and disease history will be reviewed from your medical records.
- You will be asked about any medicines you are taking including over-the-counter medicines, vitamins, or herbal treatments.
- You will be asked if you are feeling any unwanted effects.
- You will be asked about your ability to perform daily tasks such as dressing yourself and getting out of bed.
- Blood (about 3 Tablespoons) will be drawn by inserting a needle into a vein.
    - About 2 Tablespoons of blood will be used for safety laboratory testing.
    - About 1 Tablespoon of blood will be used to measure the tumor markers in your blood.
- You will be asked to provide a urine sample to measure the tumor markers in your urine. Urine samples to measure tumor markers will require a 24-hour collection.
- If you are a woman of childbearing age, blood or urine will be collected for a pregnancy test. You must have a negative pregnancy test in order to participate in this study. If you have a blood test, less than half a teaspoon of blood will be collected.

During the main part of the study:

If the tests and procedures show that you can be in the main part of the study, and you choose to take part, then you will receive pembrolizumab. Pembrolizumab will be given in cycles. Each cycle is 3 weeks (21 days).

- Pembrolizumab will be given through a vein (infused) over 30 minutes, every 3 weeks.

The following tests and procedures will be done during the main part of the study:

Cycle 1, Day 1

- You will receive pembrolizumab via an infusion over the course of 30 minutes.
- You will have a physical examination including measurement of your height, weight, and vital signs (temperature, blood pressure, respirations, and heart rate).
- You will be asked about any medicines you are taking including over-the-counter medicines, vitamins, or herbal treatments.
- You will be asked if you are feeling any unwanted effects.
- You will be asked about your ability to perform daily tasks such as dressing yourself and getting out of bed.
- Blood (about 3 Tablespoons) will be drawn by inserting a needle into a vein.
    - About 2 Tablespoons of blood will be used for safety laboratory testing.
    - About 1 Tablespoon of blood will be used to measure the tumor markers in your blood.
    - About 1 Tablespoon of blood will be used to monitor your immune system's response to the study therapy.
- If you are a woman of childbearing age, blood or urine will be collected for a pregnancy test. You must have a negative pregnancy test in order to participate in this study. If you have a blood test, less than half a teaspoon of blood will be collected.

Cycle 1, Day 8

- You will have a physical examination including measurement of your height, weight, and vital signs (temperature, blood pressure, respirations, and heart rate).
- You will be asked about any medicines you are taking including over-the-counter medicines, vitamins, or herbal treatments.
- You will be asked if you are feeling any unwanted effects.
- You will be asked about your ability to perform daily tasks such as dressing yourself and getting out of bed.
- Blood (about 3 Tablespoons) will be drawn by inserting a needle into a vein.
    - About 2 Tablespoons of blood will be used for safety laboratory testing.

Cycle 2, Cycle 3, and Cycle 4, Day 1

- You will receive pembrolizumab via an infusion over the course of 30 minutes.
- You will have a physical examination including measurement of your height, weight, and vital signs (temperature, blood pressure, respirations, and heart rate).
- You will be asked about any medicines you are taking including over-the-counter medicines, vitamins, or herbal treatments.
- You will be asked if you are feeling any unwanted effects.
- You will be asked about your ability to perform daily tasks such as dressing yourself and getting out of bed.
- About 2 Tablespoons of blood will be drawn by inserting a needle into a vein. This will be used for safety laboratory testing.
- If you are a woman of childbearing age, blood or urine will be collected for a pregnancy test. You must have a negative pregnancy test in order to participate in this study. If you have a blood test, less than half a teaspoon of blood will be collected.

Cycle 5 and all following Cycles, Day 1

- You will receive pembrolizumab via an infusion over the course of 30 minutes.
- You will have a physical examination including measurement of your height, weight, and vital signs (temperature, blood pressure, respirations, and heart rate).
- You will be asked about any medicines you are taking including over-the-counter medicines, vitamins, or herbal treatments.
- You will be asked if you are feeling any unwanted effects.
- You will be asked about your ability to perform daily tasks such as dressing yourself and getting out of bed.
- Blood (about 4 Tablespoons) will be drawn by inserting a needle into a vein.
    - About 2 Tablespoons of blood will be used for safety laboratory testing.
    - About 1 Tablespoon of blood will be used to measure the tumor markers in your blood.
    - About 1 Tablespoon of blood will be used to monitor your immune system’s response to the study therapy.
- You will be asked to provide a urine sample to measure the tumor markers in your urine. Urine samples to measure tumor markers will require a 24-hour collection.

- If you are a woman of childbearing age, blood or urine will be collected for a pregnancy test. You must have a negative pregnancy test in order to participate in this study. If you have a blood test, less than half a teaspoon of blood will be collected.
- If you show a very good response to the study drug, a sample of your bone marrow may be collected to measure how much multiple myeloma cells are in your bone marrow. This test is done by inserting a needle into your hipbone to remove a sample of bone and bone marrow (about 2 teaspoons). You will receive a medicine to numb the surface of your skin on your hip. This will take about 15-30 minutes.

When you are finished receiving pembrolizumab:

End of Treatment (within 21 days of finishing study drug)

- You will be asked about any medicines you are taking including over-the-counter medicines, vitamins, or herbal treatments.
- You will be asked if you are feeling any unwanted effects.
- You will be asked to provide a urine sample to measure the tumor markers in your urine. Urine samples to measure tumor markers will require a 24-hour collection.
- Blood (about 1 Tablespoon) will be drawn by inserting a needle into a vein and will be used for measuring tumor markers in your blood.

Safety Follow-up (30 days after End of Treatment visit)

- You will have a physical examination including measurement of your height, weight, and vital signs (temperature, blood pressure, respirations, and heart rate).
- You will be asked about any medicines you are taking including over-the-counter medicines, vitamins, or herbal treatments.
- You will be asked if you are feeling any unwanted effects.
- You will be asked about your ability to perform daily tasks such as dressing yourself and getting out of bed.
- The study doctor will review any new cancer therapy that you have started since your last dose of the study drug.
- About 2 Tablespoons of blood will be drawn by inserting a needle into a vein. This will be used for safety laboratory testing.

Long-term Follow-up (every 12 weeks after Safety Follow-Up visit; continues for up to 1 year after finishing study drug)

- You will be asked about any medicines you are taking including over-the-counter medicines, vitamins, or herbal treatments.
- You will be asked if you are feeling any unwanted effects.
- The study doctor will review any new cancer therapy that you have started since your last dose of the study drug.
- You will be asked to provide a urine sample to measure the tumor markers in your urine. Urine samples to measure tumor markers will require a 24-hour collection.
- About 1 Tablespoon of blood will be drawn by inserting a needle into a vein and will be used for measuring tumor markers in your blood.

Study location:

All study procedures will be done at UCSF Helen Diller Family Comprehensive Cancer Center.

How long will I be in the study?

You will be asked to take pembrolizumab for up to 2 years or until your disease gets worse (progresses) or you cannot tolerate the side effects. After you are finished taking pembrolizumab, the study doctor will ask you to complete follow-up visits for at least 1 year. These follow-up visits can take place over the phone, video conference, or in-person.

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. They 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 pembrolizumab 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 they believe 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 pembrolizumab. In some cases, side effects can be serious, long lasting, or may never go away. There also is a risk of death.

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

Risks related to pembrolizumab

Pembrolizumab has received FDA approval to treat certain types of cancer and is available by prescription to treat those types for which it's approved. It is not approved to treat multiple myeloma, so it is considered investigational for this use.

Pembrolizumab works by helping your immune system to fight your cancer.

However, pembrolizumab can also cause your immune system to attack normal organs and tissues in your body and can affect the way they work, which can result in side effects. These side effects may be serious (i.e., causing hospitalization or be life-threatening), may result in death, and/or may occur after you stop taking pembrolizumab. These side effects can affect more than one of your normal organs and tissues at the same time.

Keynote-183 was a randomized trial which evaluated pomalidomide and low-dose dexamethasone with or without pembrolizumab in patients with relapsed and refractory multiple myeloma. The **survival hazard ratio** is a statistical calculation used to compare one group's risk of death compared to another group's risk of death. In this case, it was used to compare the group that received pembrolizumab compared to the group that did not receive pembrolizumab. This trial showed an overall survival hazard ratio of 1.61(95% CI: 0.91, 2.85) in the pembrolizumab containing group compared to the control group which did not contain pembrolizumab. In other words, this translates to risk of death being 1.6 times higher in the pembrolizumab treated group compared to the control group (non-pembrolizumab treated group). Unlike Keynote-183 which used pembrolizumab in combination with other drugs, this current study is investigating the use of pembrolizumab alone which may or may not be associated with increased risk of death.

VERY COMMON

Out of 100 people who receive pembrolizumab, 20 or more people may have the following:

- Itching of the skin
- Loose or watery stools
- Cough

COMMON

Out of 100 people who receive pembrolizumab, at least 5 but less than 20 people may have the following:

- Joint pain
- Rash
- Fever
- Back pain
- Pain in your belly
- Loss of skin color
- Not enough thyroid hormone so you may feel tired, gain weight, feel cold, have infrequent or hard stools (hypothyroidism)
- Low levels of salt in the blood that may cause you to feel tired, feel confused, have a headache, have muscle cramps and/or feel sick to your stomach (hyponatremia)

UNCOMMON

Out of 100 people who receive pembrolizumab, at least 1 but less than 5 people may have the following:

- Inflammation of the lungs, so you may feel short of breath and cough (pneumonitis)
- Too much thyroid hormone, so you may feel anxious, feel angry, have trouble sleeping, feel weak, tremble, sweat, feel tired, have loose and watery stools (hyperthyroidism)
- Infusion reaction, where you may feel dizzy or faint, feel flushed, get a rash, have a fever, feel short of breath, experience a decrease in your blood pressure infusion at the time of receiving your infusion (IV) or just after, or have pain at the site of infusion
- Inflammation of the bowels/gut, which may cause severe pain in your belly with loose or watery stools, and black, tarry, sticky stools or stools with blood or mucus (colitis)
- Inflammation of the skin so you may have peeling of the skin, itchiness, and/or skin redness. The skin inflammation (i.e., peeling, itching and redness) could also be widespread throughout your body. More severe skin reactions may involve the inside of your mouth, the surface of your eye and genital areas, and/or may cause the top layer of your skin to peel from all over your body, which can cause severe infection (Severe skin reactions, including Stevens-Johnson syndrome or toxic epidermal necrolysis)

RARE

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

- Inflammation of the nerves that may cause pain, weakness or tingling in your hands and feet, and may spread to your legs, arms and upper body, leading to severe muscle weakness and possible temporary paralysis (Guillain-Barre syndrome)
- Inflammation of the muscles, so you may feel weak or have pain in your muscles (myositis)
- Inflammation of the pancreas (a gland in your abdomen that controls sugar levels), so you may have severe pain in the top part of your belly that may move to your back, feel sick to your stomach, and have vomiting that gets worse when you eat (pancreatitis)
- Inflammation of the eye, so you may have eye redness, blurred vision, sensitivity to light, eye pain, see floaters or have headaches (uveitis)
- Inflammation of the liver that may make you feel sick to your stomach and vomit, feel like not eating, feel tired, have a mild fever, have a pain in the right side of your belly, yellow eyes and skin, and dark urine (hepatitis)
- Inflammation of the pituitary gland (a gland in the head), which may cause you to feel sick to your stomach or have headaches, changes in your behavior, double vision, few to no menstrual cycles, weakness, vomiting and dizziness, or fainting (hypophysitis)
- Adrenal glands (glands on top of the kidneys) that may not make enough hormone, which could cause tiredness, weight loss, muscle weakness, feeling faint, having joint, muscle and bellyaches, nausea, vomiting, loose or watery stools, fever, salt craving, and sometimes darkening of the skin like a suntan (adrenal insufficiency)
- Type 1 diabetes, a condition that can cause too much sugar in your blood, feeling thirstier than usual, frequent urination, and weight loss. You are likely to need regular insulin shots.
- Inflammation of the kidney, so you may pass less urine or have cloudy or bloody urine, swelling, and low back pain (nephritis)
- Inflammation of the middle layer of your heart wall that may cause your heart to have difficulty pumping blood throughout your body, which can cause chest pain, shortness of breath, and swelling of the legs. You may experience a fast or irregular heartbeat that may cause dizziness or fainting (myocarditis)
- Inflammation of the thyroid gland, an organ that makes and stores thyroid hormones. This condition may lead to change in your heart rate, blood pressure, body temperature, and the rate at which food is converted into energy (thyroiditis)

- A condition that may make you feel weak and tired and may cause drooping of the eyelids, blurred or double vision, difficulty swallowing, slurred speech, weakness in your arms and legs, or difficulty breathing (myasthenic syndrome/myasthenia gravis including exacerbation)
- The formation of small clusters of immune cells (called granulomas) in parts of your body such as your lymph nodes, eyes, skin, or lungs (sarcoidosis)
- Inflammation of the brain with confusion and fever. This may also include: disorientation, memory problems, seizures (fits), changes in personality and behavior, difficulty speaking, weakness or loss of movement in some parts of your body, and loss of consciousness (encephalitis)
- Inflammation of the spinal cord with pain, numbness, tingling, or weakness in the arms or legs, bladder or bowel problems including needing to urinate more frequently, urinary incontinence, difficulty urinating, and constipation (myelitis)
- Inflammation of the blood vessels (vasculitis). Symptoms will depend on the particular blood vessels that are involved in the inflammatory process, for example; if it is your skin, you may get a rash. If your nerves are not getting enough blood, you could have numbness and weakness. You may also experience fever, weight loss, and fatigue.
- Low levels of parathyroid hormone (a hormone made by 4 tiny glands in your neck) which may result in low blood calcium and cause muscle cramps or spasms**;** fatigue or weakness; numbness, tingling or burning in your fingertips, toes or lips (hypoparathyroidism)
- Inflammation of the stomach (gastritis). You may have pain in your belly, feel full, or sick to your stomach. You may also experience nausea, vomiting or loss of appetite.
- Low number of red blood cells (cells that carry oxygen) due to destruction of red blood cells (hemolytic anemia). You may feel weak, tired, lightheaded, short of breath, or have a fast heartbeat. You may also experience difficulty with physical exercise, pale or yellow skin, dark urine, or fever.
- Not enough pancreatic enzymes (proteins that break down food) that leads to poor digestion of food (exocrine pancreatic insufficiency). You may have bloating, gas, discomfort in your belly, diarrhea, abnormal stool that is oily, or weight loss.

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

- Inflammation of the joints which may include joint pain, stiffness and/or swelling (arthritis)
- Severe responses of the immune system that cause the body to attack its own blood cells, spleen, liver, lymph nodes, skin and brain. This may include fever,

rash, inflammation of the liver, yellowing of the skin, an enlarged liver and spleen, low blood counts, and enlarged lymph nodes. The nervous system may also be affected and cause confusion, seizures, and even coma (hemophagocytic lymphohistiocytosis)

- Changes in eyesight, eye pain, whitish patches on the skin and hearing loss (Vogt-Koyanagi-Harada syndrome)
- Inflammation and scarring of the bile ducts (tubes that carry digestive fluid that is made in the liver). This can cause symptoms similar to those seen with inflammation of the liver (hepatitis) such as pain in the right side of your belly, yellow eyes and skin, feeling tired, and itching (sclerosing cholangitis).
- Inflammation or swelling of the nerve fibers of the eye which send visual information from your eye to your brain. This health condition often has a sudden onset of vision loss, loss of color vision, pain when moving your eyes, and/or loss of peripheral vision. It may affect one or both eyes at the same time (optic neuritis). In most cases, the vision loss is temporary and can resolve with drug discontinuation and supportive medications, but there is a small risk of permanent symptoms.

Patients treated with pembrolizumab BEFORE going on to receive an allogeneic stem cell transplant (a procedure in which a person receives blood-forming stem cells from a donor) should inform their transplant physicians that they have received pembrolizumab in the past.

In patients with any hematologic malignancy (cancers of the blood like Hodgkin lymphoma, multiple myeloma): there is a potential for an increased risk of severe complications following allogeneic stem cell transplant in patients who previously received pembrolizumab BEFORE an allogeneic stem cell transplant.

Reports of clotting of blood within the liver and severe graft versus host disease (which can include skin, liver, and gastrointestinal symptoms), including death, have been received for patients who received pembrolizumab BEFORE an allogeneic stem cell transplant.

Risks related to Study Procedures

- INTRAVENOUS LINE: The temporary placement of an intravenous line may cause discomfort when inserting the needle, as well as bruising; bleeding; and rarely, infection.
- BLOOD DRAWS: The risks of drawing blood include temporary discomfort from the needle stick, bruising, and rarely, infection.
- REPRODUCTIVE: You should not become pregnant or father a baby while on this study because the drugs in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. It is important to understand

that you need to use birth control while on this study. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study.

- BONE MARROW BIOPSY: When you have a bone marrow biopsy, there may be some discomfort during and after collection of the sample. You may experience pain, bleeding and swelling. Numbing medicine may be given with a syringe near the site of the bone marrow biopsy. You may have an increased risk of developing an infection at the sample site.
- UNKNOWN: 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 pembrolizumab will be more useful against your type of 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 pembrolizumab 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?

Your other choices may include:

- Getting treatment or care for your cancer without being in a study.
- Taking part in another study.
- Getting no treatment.
- Getting comfort care, also called palliative care. This type of care helps 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.

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

How will my specimens and information be used?

Researchers will use your specimens and information to conduct this study. Specimens and information gathered during this research study will only be used for this study. They will not be shared with other researchers.

Research Results: There is information at the end of this consent document about an **optional** opportunity to opt into allowing us to store your leftover specimens from this study for unknown future research.

How will information about me be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. If you do not have a UCSF medical record, one will be created for you. Your signed consent form and some of your research tests will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation and any information added to your medical record as a result of your participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records and may be added to your medical record. 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.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of Merck
- Representatives of the University of California
- Representatives of the Food and Drug Administration (FDA)

Are there any costs to me for taking part in this study?

Two types of procedures will be done during this study. Some are part of your standard medical care and others are only for research. You or your insurer will be billed for the standard medical care. You will be responsible for your co-pays, deductibles, and any other charges that your insurer will not pay. There is a possibility that your insurer may not cover all standard medical care costs if you are receiving medical services out of network. Any procedures done only for research will not be charged to you or your insurer.

If you have questions about what costs you will be responsible for, please talk with the study investigator before deciding to enroll in the study. Depending on the type of study, some of your costs could be substantial.

Merck will provide pembrolizumab at no cost to you.

Will I be paid for taking part in this study?

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

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, Alfred Chung, MD, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call them - Alfred Chung, MD [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 Institutional Review Board 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, Alfred Chung, MD[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 Institutional Review Board at 415-476-1814.

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

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OPTIONAL RESEARCH PARTICIPATION

This section of the informed consent is about optional future contact of participants in the main study. You can still be in the main study even if you say "no" to allowing optional future contact.

Future Contact

We want to know if we may contact you in the future to see if you are interested in participating in other research studies.

If you agree and we contact you to tell you about a study, you have no obligation to actually participate in any study. You can decide when you are told about the study if you want to receive more information about the study. There would be a new consent process for that study.

If at any time you decide you no longer want to be contacted about future studies, please let us know by calling Alfred Chung, MD [redacted].

Storage of Leftover Specimens for Future Unknown Research

Researchers will use your blood and tissue specimens and information to conduct this study. If there are leftover samples, we want to know if you will allow us to store them in a repository, also called a 'tissue bank,' at UCSF and share them with other researchers so they can use them for other cancer studies in the future.

We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share the de-identified information and specimens.

Your blood and tissue specimens will be stored in a repository, also called a 'tissue bank,' at UCSF. The manager of the tissue bank and select tissue bank staff members will have access to your specimens and information about you, but they will not release any identifying information about you to researchers using your specimens. We may give your specimens and certain medical information about you (for example, diagnosis, blood pressure, age if less than 85) to other scientists or companies not at UCSF, including to an unrestricted or controlled-access government health research database, but we will not give researchers outside of UCSF your name, address, phone number, or any other identifiable information. Your specimens and information will be kept indefinitely until they are used up or destroyed.

Research results from these studies will not be returned to you and will not be put in your medical record. The research will not change the care you receive.

Researchers may use your blood and tissue specimens to look at all your DNA (this is called “whole genome sequencing”). DNA contains information that determines things like eye color, height, or disease risk that are passed on from parent to child. Genetic information (also known as genotype data) and the medical record data (also known as phenotype data) may be shared broadly in a coded form for future genetic research or analysis.

Donating data and specimens may involve a loss of privacy, but information about you will be handled as confidentially as possible. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security. 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. Taking part in a genetic study may also have a negative impact or unintended consequences on family or other relationships. It is possible that future research 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 a particular race, ethnicity, or sex. In some cases, this could reinforce harmful stereotypes.

There will be no direct benefit to you from allowing your specimens and data to be kept and used for future research. However, we hope we will learn something that will contribute to the advancement of science and understanding of health and disease. If your specimens, the data, or any new products, tests, or discoveries that result from this research have potential commercial value, you will not share in any financial benefits.

If you decide later that you do not want your information to be used for future research, you can notify the investigator in writing at,

Alfred Chung, MD
University of California San Francisco
[redacted]
San Francisco, CA 94143
[redacted]

and any remaining specimens and data will be destroyed. However, we cannot retract any specimens and data that have been shared with other researchers.

Making Your Choice

Please read the sentence below and mark your choice by putting 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 415-476-1814.

No matter what you decide to do, it will not affect your care or your participation in the main study.

1. **Someone may contact me in the future about taking part in more research.**

YES	***NO***

2. **I allow my specimens and data to be kept and used for future research.**

YES	***NO***

****

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