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

Study Title: Phase II Study of Daratumumab in Combination with Azacitidine and Dexamethasone in Relapsed/Refractory Multiple Myeloma Patients Previously Treated with Daratumumab

Principal Investigator:	Alfred Chung, MD [redacted] San Francisco, CA 94143 [redacted]

This is a clinical research study. Your study doctor(s) Swetha Kambhampati, MD and Alfred Chung, MD from the UCSF Department of Hematology, will explain the study to you.

STUDY SUMMARY

Introduction: We are asking you to consider taking part in a research study being done by Drs. Swetha Kambhampati and Alfred Chung at UCSF. You are being asked to take part in this study because you have relapsed and refractory multiple myeloma meaning your cancer has returned and it is no longer responding to treatment.

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

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.

Purpose of the study:

The purpose of this study is to determine if the combination of daratumumab, azacitidine and dexamethasone is safe and effective for treating patients with relapsed and refractory multiple myeloma who were previously treated with daratumumab.

Study Procedures:
You must be screened to see if you can be in this study. If you are in the study, you must provide two bone marrow biopsies, blood samples, and information about your current and past medications, treatments, and surgeries.

The main study is divided into four phases, Pre-Induction, Induction, Consolidation and Maintenance phases. Each phase is divided into four-week Cycles.

1. **Pre-Induction, Cycle 1 Days -7 to -3:** You will receive your first dose of azacitidine on 5 of the 7 days before Cycle 1 Day 1. Azacitidine is given by intravenous (IV) infusion or by injection under the skin (which is also called subcutaneous injection).

2. **Induction, Cycles 1 and 2:** On Days 1, 8, 15, and 22 of each Cycle you will receive daratumumab and dexamethasone. Daratumumab is given by injection under the skin. Dexamethasone is given by IV or taken by mouth. You will also receive azacitidine for five consecutive days of each Cycle, on Days 22 to 26. After Cycle 2, depending on your response to the study treatment the study doctor will tell you whether dexamethasone should continue weekly, be reduced, or stop.

3. **Consolidation, Cycles 3-6:** You will receive daratumumab on Days 1 and 15 of each Cycle. You will receive dexamethasone as needed. During Cycle 3 you will receive azacitidine every day on Days 22 to 26. During Cycles 5 and 6 you will receive azacitidine every day on Days 1 – 5.

4. **Maintenance, Cycles 7 and beyond:** You will receive daratumumab on Day 1. You will receive dexamethasone as needed. You will also receive azacitidine every day on Days 1 to 5.

In addition, the main study procedures include two bone marrow biopsies, blood sample collection, and collecting information about your current and past medications, treatments and/or surgeries.

You will be in this study for about 20 - 24 months depending on how well you respond to the study treatment and you will visit the research site approximately 40 - 45 times.

Possible Risks: There are risks to taking part in a research study. Some of the most likely risks of the study drugs include:

Daratumumab

- Neutropenia (low neutrophil count)
- Thrombocytopenia (decrease in the number of platelets)
- Interference with pre-transfusion blood testing
- Liver infection (hepatitis) in those patients who are carriers of the hepatitis B virus

Azacitidine

- Anemia which may require blood transfusion
- Constipation, diarrhea, nausea, vomiting
- Tiredness, fever

Dexamethasone

- High blood pressure, retaining water, changes in salt or potassium levels in your body
- Changes in vision, trouble seeing, eye pain

There is also risk of loss of privacy. We will test your blood during screening and if we find you have a new case of Hepatitis B/C we must report it to the San Francisco Health Department, as described on page 23.

We'll tell you about the other risks later in this consent form.

Possible Benefits:

You may benefit from participating in the study, but this cannot be guaranteed.

Your Other Options: You do not have to participate in this study. Your other choices may include:

- Getting treatment or care for your condition without being in a study.
- Taking part in another study.
- Getting no treatment or receiving comfort care to relieve your symptoms and discomfort.

Please talk to your doctor about your choices before agreeing to participate in this study.

The following section 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.

DETAILED STUDY INFORMATION

This part of the consent form gives you more detailed information about what the study involves.

You are being asked to take part in this study because you have relapsed and refractory multiple myeloma (RRMM) meaning your cancer has returned and it is no longer responding to treatment.

Why is this study being done?

The purpose of this study is to find out how your multiple myeloma responds to receiving daratumumab in combination with azacitidine and dexamethasone and what good and/or bad effects the combination has on patients with relapsed and refractory multiple myeloma.

Daratumumab is an antibody made up of immune cells that attaches to a protein on your myeloma cell, called CD38. CD38 is found in higher levels on your tumor cells than on your normal cells. Daratumumab prevents the growth of tumors who have high levels of CD38 by causing those cells to die. Daratumumab is commercially approved for the treatment of multiple myeloma and AL amyloidosis.

Azacitidine has been shown in studies to help restore normal cell function and growth in your cells. Azacitidine is FDA approved for the treatment of myelodysplastic syndrome and in combination with venetoclax for newly diagnosed acute myeloid leukemia in patients who were ≥ 75 years of age or had comorbidities that prevented the use of intensive induction chemotherapy. In this study, we hope that azacitidine will help increase the levels of CD38 on your tumor cells to increase the function of daratumumab to attach to those tumor cells to help destroy them.

Dexamethasone is a steroid that helps decrease inflammation and lowers your normal immune response. Dexamethasone is being used in this study to help reduce the effect of any injection-related reactions.

If you sign this consent form to participate in the study, you will do tests and procedures to make sure that it is okay for you to participate in this study- this is called screening. After screening, you will begin receiving the study drugs.

Azacitidine will be given for 5 consecutive days before the start of Cycle 1 during Days -7 to -3. During Cycles 1 to 3, you will be given azacitidine for 5 consecutive days on Days 22 - 26. Starting Cycle 5, azacitidine will be given for 5 consecutive days on Days 1 to 5. Azacitidine is given by intravenous (IV) infusion or by injection under the skin (also called subcutaneous injection).

Daratumumab will be given weekly during the Induction phase of Cycles 1 to 2 on Days 1, 8, 15, 22 and every 2 weeks during the Consolidation phase of Cycles 3 to Cycle 6 on Days 1 and 15 and every 4 weeks during the Maintenance phase in Cycle 7 and beyond on Day 1. Daratumumab is given by injection under the skin.

Dexamethasone will be given by IV infusion or taken by mouth every week for the first 2 Cycles of study treatment. Before you are given daratumumab, you will be given dexamethasone as a pre--medication. During the weeks you are not receiving daratumumab, you may be told to take dexamethasone by mouth. After Cycle 2, depending on your response to the study treatment, the study doctor will tell you whether dexamethasone should continue weekly, be reduced, or stop.

Janssen, the manufacturer of daratumumab, is supplying daratumumab at no cost to study participants, and is providing funding to UCSF for this study, which will be used by UCSF to purchase commercial supply of azacitidine for the study.

How many people will take part in this study?

About 23 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 complete physical exam (including height and weight) and your current symptoms will be reviewed.
- You will have your vital signs checked (temperature, blood pressure, pulse, and breathing rate).
- You will be asked about your medical history which includes a review of medications, assessment of your disease, past procedures, past treatments, and current baseline medical conditions.
- You will be asked about your basic daily activities to determine your general health, how you have been feeling, and about your daily activities (performance status).
- If you are a woman of child-bearing potential you will have a urine or blood (1 teaspoon) pregnancy test within 7 days of starting the study drug(s).
- You will have a total of 3 tablespoons of blood be taken by inserting a needle into a vein in your arm for routine safety tests, Hepatitis B/C, and assessment of your disease.
- You will have a skeletal scan of your skull, spinal cord, long bones, pelvis and chest, if your study doctor finds it necessary.
- You will have an MRI, contrast-enhanced CT, or PET/CT imaging of the soft tissue or bony skeleton, if your study doctor finds it necessary.
- MRI scan: A Magnetic Resonance Imaging (MRI) scan takes an image of your head or body to observe the location and size of your tumor. For the MRI scan, you may be given a 'contrast material' (a special dye that makes it easier for doctors to see different tissues in your body). Gadolinium is contrast material that causes some tumors to appear much brighter than normal tissue on MRI scans (these tumors may not be visible without gadolinium). The contrast material may be given to you in your arm through an intravenous catheter (a tiny tube inserted into a vein). You will then lie down on a narrow bed which will be placed in a tunnel that is 6 feet long by 22 inches wide and open at each end. You will lie there quietly for about one hour, during which time you will hear a loud machine-like noise. The MRI scan is done in the radiology department and takes approximately an hour and a half to complete.

- PET/CT scan: For this procedure, an IV is started in the hand. A small amount of radioactive chemical (glucose) is injected into the blood stream. Once the glucose is injected, you will be asked to wait for about an hour to allow for glucose to distribute in the body. Then you will be asked to lie down on a table and the body is scanned. The total time for this procedure is about 2-3 hours.
- A CT scan uses special x-ray equipment to make detailed pictures of body tissues and organs. For the CT scan, you may be given a "contrast material" (a special dye that makes it easier for doctors to see different tissues in your body). The contrast material may be given orally, intravenously, or rectally (less likely). Oral contrast material is given to you to drink and is used to help outline the stomach and intestines. Intravenous (IV) contrast material is given to you by injecting the contrast material into a line which is attached to a needle in your arm, and is used to get clearer pictures of your body cavity. A rectal contrast fills up the loops of your lower bowel so the doctors can see your tumor better. After you have been given the contrast material (either by mouth, by vein, or rectum), you will lie flat on a table that will move you into the CT scan machine. You will be asked to lie still and may be asked to hold your breath for a few seconds. The CT scan is done in the Radiology Department and takes about half an hour.
- You will have a biopsy within 14 days of you receiving azacitidine dose. A sample of your bone marrow will be collected for disease assessment (to look for the presence of tumor cells inside the bone marrow) and to measure the amount of CD38, the marker which daratumumab binds to in order to kill your myeloma cells, is in your bone marrow. This test is done by inserting a needle into your hip bone 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.

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 begin receiving azacitidine, daratumumab and dexamethasone. The study is divided into four parts: Pre-Induction, Induction, Consolidation and Maintenance phases.

During the Pre-Induction phase, you will come in on Days -7 to -3 of Cycle 1 to receive your first dose of azacitidine for 5 consecutive days. Azacitidine is given by IV infusion or by injection under the skin (also called subcutaneous injection).

During the Induction phase, you will come in on Days 1, 8, 15, and 22 during Cycles 1-2 to receive daratumumab as well as receive dexamethasone. Daratumumab is given by injection under the skin. Dexamethasone is given by IV or taken by mouth. You will also receive azacitidine for five consecutive days during Cycles 1 and 2 on Days 22 – 26. After Cycle 2, depending on your response to the study treatment, the study doctor will tell you whether dexamethasone should continue weekly, be reduced, or stop.

During the Consolidation phase, you will come in on Days 1 and 15 during Cycles 3 through 6 to receive daratumumab. You will also receive azacitidine for five consecutive days on Days 22 – 26 during Cycle 3 and Days 1 – 5 during Cycles 5 – 6.

During the Maintenance phase, you will come in on Day 1 during Cycles 7 and beyond to receive daratumumab. You will also receive azacitidine for five consecutive days on Days 1 to 5 during Cycles 7 and beyond.

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

Pre-Induction Phase:

Cycle 1, Day – 7 (1 week before daratumumab administration)

Items marked with an asterisk (*) will occur daily on Day -7 to -3 while the other items are only performed on Day -7

- You will have a complete physical exam (including weight) and your current symptoms will be reviewed.
- You will have your vital signs checked (temperature, blood pressure, pulse, and breathing rate).*
- You will be asked about the medications you are currently taking, including over-the-counter medicines, vitamins, or herbal treatments.
- You will be asked about your medical history which includes a review of medications, assessment of your disease, past procedures, past treatments, and current baseline medical conditions.
- You will be asked about your basic daily activities to determine your general health, how you have been feeling, and about your daily activities (performance status).
- You will have a total of 3 tablespoons of blood be taken by inserting a needle into a vein in your arm for routine safety tests and assessment of your disease.
- You will have an MRI, contrast-enhanced CT, PET/CT imaging of the soft tissue or bony skeleton, or skeletal survey (a series of x-rays to check for bone lesions), only if your study doctor finds it necessary for your myeloma as standard of care
- You will receive azacitidine via IV infusion or injection under the skin for 5 consecutive days, (Cycle 1, Day – 7 through Cycle 1, Day – 3).*

Induction Phase:

Cycles 1 and 2, Day 1

- You will have a complete physical exam (including weight) and your current symptoms will be reviewed.
- You will have your vital signs checked (temperature, blood pressure, pulse, and breathing rate).

- You will be asked about the medications you are currently taking, including over-the-counter medicines, vitamins, or herbal treatments.
- You will be asked about your basic daily activities to determine your general health, how you have been feeling, and about your daily activities (performance status).
- If you are a woman of childbearing potential you will have a urine or blood (1 teaspoon) pregnancy test before the administration of the study drug(s).
- You will have a total of 3 tablespoons of blood be taken by inserting a needle into a vein in your arm for routine safety tests and assessment of your disease.
- You will have an MRI, contrast-enhanced CT, PET/CT imaging of the soft tissue or bony skeleton, or skeletal survey (a series of x-rays to check for bone lesions) only if your study doctor finds it necessary for your myeloma as standard of care
- You will have a second bone marrow biopsy before you receive daratumumab. A sample of your bone marrow will be collected to measure the amount of CD38, the marker which daratumumab binds to in order to kill your myeloma cells, is in your bone marrow (Cycle 1, Day 1 only).
- You will take dexamethasone by mouth or it will be given via an IV infusion before receiving daratumumab.
- You will receive daratumumab by injection under the skin.

<u>Cycles 1 and 2, Days 8 and 15</u>

- You will have your weight recorded and your current symptoms will be reviewed.
- You will have your vital signs checked (temperature, blood pressure, pulse, and breathing rate).
- You will be asked about the medications you are currently taking, including over-the-counter medicines, vitamins, or herbal treatments.
- You will have a total of 2 tablespoons of blood be taken by inserting a needle into a vein in your arm for routine safety tests.
- You will have an MRI, contrast-enhanced CT, PET/CT imaging of the soft tissue or bony skeleton, or skeletal survey (a series of x-rays to check for bone lesions) only if your study doctor finds it necessary for your myeloma as standard of care
- You will take dexamethasone by mouth or it will be given via IV infusion before receiving daratumumab.
- You will receive daratumumab by injection under the skin.

<u>Cycles 1 and 2, Day 22</u>

Items marked with an asterisk (*) will occur daily on Days 22 through 26 while the other items are only performed on Day 22

- You will have your weight recorded and your current symptoms will be reviewed.
- You will have your vital signs checked (temperature, blood pressure, pulse, and breathing rate).*

- You will be asked about the medications you are currently taking, including over-the-counter medicines, vitamins, or herbal treatments.
- You will have a total of 2 tablespoons of blood be taken by inserting a needle into a vein in your arm for routine safety tests.
- You will have an MRI, contrast-enhanced CT, PET/CT imaging of the soft tissue or bony skeleton, or skeletal survey (a series of x-rays to check for bone lesions) only if your study doctor finds it necessary for your myeloma as standard of care
- You will take dexamethasone by mouth or it will be given via IV infusion before receiving daratumumab (Cycles 1 and 2, Days 22, only). After you complete Cycle 2, Your study doctor will discuss with you reducing or stopping your dose of dexamethasone, depending on your response to study treatment.
- You will receive daratumumab by injection under the skin (Cycles 1 and 2, Days 22, only).
- You will receive azacitidine via IV infusion or injection under the skin for 5 consecutive days, (Cycles 1 and 2, Days 22 through 26).*

Consolidation Phase:

Cycles 3 and 4, Day 1

- You will have a complete physical exam (including weight) and your current symptoms will be reviewed.
- You will have your vital signs checked (temperature, blood pressure, pulse, and breathing rate).
- You will be asked about the medications you are currently taking, including over-the-counter medicines, vitamins, or herbal treatments.
- You will be asked about your basic daily activities to determine your general health, how you have been feeling, and about your daily activities (performance status).
- If you are a woman of childbearing potential you will have a urine or blood (1 teaspoon) pregnancy test before the administration of the study drug(s).
- You will have a total of 3 tablespoons of blood be taken by inserting a needle into a vein in your arm for routine safety tests and assessment of your disease.
- If you have a resolved hepatitis infection, you will be asked to take a follow-up hepatitis test.
- You will have an MRI, contrast-enhanced CT, PET/CT imaging of the soft tissue or bony skeleton, or skeletal survey (a series of x-rays to check for bone lesions) only if your study doctor finds it necessary for your myeloma as standard of care
- You will receive dexamethasone as needed, by mouth or via IV infusion.
- You will receive daratumumab by injection under the skin.

Cycles 3 and 4, Day 15

- You will have your weight recorded and your current symptoms will be reviewed.
- You will have your vital signs checked (temperature, blood pressure, pulse, and breathing rate).
- You will be asked about the medications you are currently taking, including over-the-counter medicines, vitamins, or herbal treatments.
- You will have a total of 2 tablespoons of blood be taken by inserting a needle into a vein in your arm for routine safety tests.
- You will have an MRI, contrast-enhanced CT, PET/CT imaging of the soft tissue or bony skeleton, or skeletal survey (a series of x-rays to check for bone lesions) only if your study doctor finds it necessary for your myeloma as standard of care
- You will receive dexamethasone as needed, by mouth or via IV infusion.
- You will receive daratumumab by injection under the skin.

<u>Cycle 3, Day 22</u>

Items marked with an asterisk (*) will occur daily on Days 22 through 26 while the other items are only performed on Day 22

- You will have your weight recorded and your current symptoms will be reviewed.
- You will have your vital signs checked (temperature, blood pressure, pulse, and breathing rate).*
- You will be asked about the medications you are currently taking, including over-the-counter medicines, vitamins, or herbal treatments.
- You will have a total of 2 tablespoons of blood be taken by inserting a needle into a vein in your arm for routine safety tests.
- You will have an MRI, contrast-enhanced CT, PET/CT imaging of the soft tissue or bony skeleton, or skeletal survey (a series of x-rays to check for bone lesions) only if your study doctor finds it necessary for your myeloma as standard of care.
- You will receive azacitidine via IV infusion or by injection under the skin for 5 consecutive days, (Cycle 3, Days 22 – 26, only).*

<u>Cycles 5 and 6, Day 1</u>

Items marked with an asterisk (*) will occur daily on Days 1 to 5 while the other items are only performed on Day 1

- You will have a complete physical exam (including weight) and your current symptoms will be reviewed.
- You will have your vital signs checked (temperature, blood pressure, pulse, and breathing rate).*
- You will be asked about the medications you are currently taking, including over-the-counter medicines, vitamins, or herbal treatments.
- You will be asked about your basic daily activities to determine your general health, how you have been feeling, and about your daily activities (performance

status).

- If you are a woman of child-bearing potential you will have a urine or blood (1 teaspoon) pregnancy test before the administration of the study drug(s).
- You will have a total of 3 tablespoons of blood be taken by inserting a needle into a vein in your arm for routine safety tests and assessment of your disease.
- You will have an MRI, contrast-enhanced CT, PET/CT imaging of the soft tissue or bony skeleton, or skeletal survey (a series of x-rays to check for bone lesions) only if your study doctor finds it necessary for your myeloma as standard of care.
- You will receive dexamethasone as needed, by mouth or via IV infusion.
- You will receive daratumumab by injection under the skin.
- You will receive azacitidine via IV infusion or by injection under the skin for 5 consecutive days, (Cycles 5 and 6, Days 1 to 5). *

Cycles 5 and 6, Day 15

- You will have your weight recorded and your current symptoms will be reviewed.
- You will have your vital signs checked (temperature, blood pressure, pulse, and breathing rate).
- You will be asked about the medications you are currently taking, including over-the-counter medicines, vitamins, or herbal treatments.
- You will have a total of 2 tablespoons of blood be taken by inserting a needle into a vein in your arm for routine safety tests.
- You will have an MRI, contrast-enhanced CT, PET/CT imaging of the soft tissue or bony skeleton, or skeletal survey (a series of x-rays to check for bone lesions) only if your study doctor finds it necessary for your myeloma as standard of care
- You will receive dexamethasone as needed, by mouth or via IV infusion.
- You will receive daratumumab by injection under the skin.

Maintenance Phase:

Cycles 7 and beyond, Day 1

Items marked with an asterisk (*) will occur daily on Days 1 to 5 while the other items are only performed on Day 1

- You will have a complete physical exam (including weight) and your current symptoms will be reviewed.
- You will have your vital signs checked (temperature, blood pressure, pulse, and breathing rate).*
- You will be asked about the medications you are currently taking, including over-the-counter medicines, vitamins, or herbal treatments.
- You will be asked about your basic daily activities to determine your general health, how you have been feeling, and about your daily activities (performance status).

- If you are a woman of child-bearing potential you will have a urine or blood (1 teaspoon) pregnancy test before the administration of the study drug(s).
- You will have a total of 3 tablespoons of blood be taken by inserting a needle into a vein in your arm for routine safety tests and assessment of your disease.
- You will have an MRI, contrast-enhanced CT, PET/CT imaging of the soft tissue or bony skeleton, or skeletal survey (a series of x-rays to check for bone lesions) only if your study doctor finds it necessary for your myeloma as standard of care.
- You will receive dexamethasone as needed, by mouth or via IV infusion.
- You will receive daratumumab by injection under the skin.
- You will receive azacitidine via IV infusion or by injection under the skin for 5 consecutive days (Cycles 7 and beyond, Days 1 to 5).*

<u>When you are finished receiving daratumumab and azacitidine:</u>

- You will have your vital signs checked (temperature, blood pressure, pulse, and breathing rate) and your current symptoms will be reviewed.
- You will be asked about the medications you are currently taking, including over-the-counter medicines, vitamins, or herbal treatments.
- If you are a woman of childbearing potential you will have a urine or blood (1 teaspoon) pregnancy test before the administration of the study drug(s).
- You will have a total of 3 tablespoons of blood be taken by inserting a needle into a vein in your arm for routine safety tests and assessment of your disease.
- If you have a resolved hepatitis infection, you will be asked to take a follow-up hepatitis test.
- You will have an MRI, contrast-enhanced CT, PET/CT imaging of the soft tissue or bony skeleton, or skeletal survey (a series of x-rays to check for bone lesions) only if your study doctor finds it necessary for your myeloma as standard of care.

You will be followed every 4 weeks for up to one year after stopping study treatment. You will be contacted by telephone or when you come to clinic at least every 4 weeks at minimum to assess your disease.

<u>Study location:</u>

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

How long will I be in the study?

You will be asked to receive study drugs for about 20 - 24 months depending on how well you respond to the study treatment and you will visit the research site approximately 40 - 45 times. If the study drugs are stopped or you withdraw from the study, you will be followed until any side effects from the study drugs have resolved.

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. 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 daratumumab and azacitidine 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 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 daratumumab and azacitidine. 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 Associated with Daratumumab

Any drug has risks and side effects which may vary from person to person. Side effects may be mild or very severe. Most side effects will go away after treatment is stopped, but some may be long lasting. Side effects seen on research studies can result from a patient's disease, the drug under study, other drugs you are taking, other diseases you have, or a combination of these. This section gives you the information known so far about side effects seen with daratumumab.

As of November 15, 2021, approximately 5839 clinical trial patients have been treated with daratumumab IV (intravenous directly into the vein) or SC (subcutaneous, underneath the skin of the abdomen). Of these 5839 patients about 1878 received daratumumab alone, and about 3961 patients received daratumumab in combination with other therapies.

Not all the possible side effects and risks related to daratumumab are known. New side effects may happen. You will be watched closely and you will receive appropriate care if side effects happen. Please tell your study doctor if you have any of the side effects described below or any other ones not listed. You will be told of any new findings that

may affect your decision to continue in this study.

The following side effects are observed when daratumumab was given to patients either alone or in combination with other drugs.

Very common side effects with daratumumab (affects more than 1 in 10 persons)

- Infection of the upper respiratory tract such as nose, sinuses throat or upper airway
- Infection of the lungs (pneumonia)
- Infection of the lower airway (bronchitis)
- Low white blood cells (including neutrophils and lymphocytes); may increase the risk of getting an infection (see information below)
- Low platelets; may increase the risk of bleeding and bruising (see information – “Blood Cell Effects” below)
- Low red blood cells (anemia)
- Decreased appetite
- Sleeplessness (insomnia)
- Abnormal sensation including numbness/tingling of hands, feet or limbs (sensory neuropathy, paresthesia)
- Headache
- Cough
- Shortness of breath (dyspnea), including wheezing
- Diarrhea
- Constipation
- Nausea
- Vomiting
- Rash, a noticeable change in the texture or color of your skin
- Back Pain
- Joint pain
- Muscle spasms
- Swelling of hands, feet or limbs
- Fatigue or lack of energy
- Weakness, lack of strength
- Fever

Common side effects with daratumumab (affects 1 to 10 in 100 persons)

- Urinary tract infection
- Influenza or flu like symptoms
- Sepsis (a life-threatening condition that arises when the body's response to an infection injures its own tissues and organs)
- Hypogammaglobulinemia, a condition with your immune system in which not enough gamma globulin proteins (also known as antibodies) are produced. Decreases in gamma globulin proteins can increase the risk of infections
- High blood glucose levels
- Low blood calcium levels
- Loss of body fluids, also known as dehydration
- Dizziness
- Fainting
- Irregular heartbeat (atrial fibrillation)
- High blood pressure
- Fluid in lungs (pulmonary edema)
- Inflammation of the pancreas (pancreatitis)
- Itchy skin
- Muscular pain in the chest
- Chills
- Infusion-related reaction (see information – “Infusion-Related Reactions” below)
- Injection site reaction: local reaction reported as mild pain or burning sensation at the site of injection in the abdominal wall. Redness and hardening of the skin at the injection site was also observed and usually disappeared within a few hours after the administration

Uncommon side effects with daratumumab (affects 1 to 10 in 1,000 persons)

- Cytomegalovirus infection (see information below)
- Liver infection (hepatitis) in those patients who are carriers of the hepatitis B virus

Infusion-Related Reactions

An antibody is a large protein that is generated as part of the normal immune system to neutralize foreign objects such as bacteria and viruses. Daratumumab is an antibody designed to specifically target and eliminate a specific harmful object in your body, in this case cancerous plasma cells. A non-local, hypersensitivity reaction to daratumumab that occurs during or shortly after an administration (IV or SC) is called an infusion-related reaction. It usually occurs during or within the first few hours after the start of the first administration. However, delayed reactions can happen up to 3-4 days

after the dose administration. These reactions can be life-threatening and fatal outcomes have been reported.

Signs and symptoms of infusion-related reactions may include:

- Respiratory symptoms, such as stuffy nose, cough, throat irritation
- Chills
- Vomiting
- Nausea

Most of the observed infusion-related reactions were mild or moderate, and ended by temporarily stopping the administration and/or giving medicines to treat the symptoms. Tell your doctor right away if you have above mentioned symptoms.

If you have a breathing problem now or had breathing problems in the past (like chronic obstructive pulmonary disease (COPD) or asthma), you should tell your study doctor. Also, if you start to have breathing problems while you are on the study you should tell your study doctor right away.

Severe reactions have occurred, including narrowing and obstruction of the respiratory airway (bronchospasm), low level of oxygen (hypoxia), shortness of breath, high blood pressure, swelling in the throat and fluid in the lungs (pulmonary edema). Your study doctor and their staff will be ready to treat such a reaction in case it happens. In the future, you should tell any doctor you visit that you received daratumumab (an antibody) in this research study and if you had an allergic reaction including an anaphylactic reaction, the worst case of allergic reaction.

Anaphylactic reaction
Anaphylactic reaction is a serious allergic reaction that can develop quickly (in minutes to a few hours) and may cause **death**. Usually a combination of the following side effects occurs:

- An itchy rash, throat or tongue swelling
- Shortness of breath
- Vomiting
- Lightheadedness
- Low blood pressure

This type of reaction is for example seen when one is allergic to a bee sting or certain foods like peanuts.

Please inform your doctor immediately if you experience any of these signs and symptoms.

Anaphylactic reactions were rarely reported when commercially available daratumumab was used outside of clinical trials (also called post marketing experience). The reported cases of anaphylactic reaction were believed to be a more severe form of infusion-related reactions. More than 227,000 patients globally have been treated with daratumumab. Anaphylactic reaction has not been reported in clinical studies; therefore, the frequency is not known.

The manufacturer will continue to monitor infusion-related reactions and make changes to the way daratumumab is administered and/or recommend additional medications as necessary.

Blood Cell Effects
Daratumumab can decrease white blood cell counts which help fight infections, and blood cells called platelets which help to clot blood. Tell your healthcare provider if you develop any symptoms of infection such as fever or any symptoms of decreased platelet counts such as bruising or bleeding.

Infection
Different kinds of infection have been seen in patients receiving daratumumab. Most of them are respiratory tract infections. If you have an infection now, have a history of frequent infections, or if you feel sick, you should tell your study doctor right away. The majority of the observed infections so far were mild or moderate. Severe infections such as pneumonia and sepsis have also been reported.

Certain infections with viruses, such as shingles (Herpes Zoster virus) and cytomegalovirus, and liver infection (hepatitis B virus) have been observed with daratumumab. Patients who have had prior exposure to hepatitis B virus are at increased risk of recurrence of the virus. Your doctor will test you for the hepatitis B virus before beginning treatment on this study. If you test positive for the virus, you will be e closely monitored for signs of infections during daratumumab treatment and until 6 months after the last dose of daratumumab, and you will be treated, if appropriate, by your doctor.

Heart problems in patients with light chain (AL) amyloidosis
Heart problems, in some cases fatal, have occurred. Your study doctor will monitor you closely during treatment with daratumumab. Call your study doctor right away if any of the following symptoms occur: chest pain, feeling faint, swollen legs, shortness of breath, or abnormal heart rhythm.

Blood transfusions:
If you need a blood transfusion, you will have a blood test first to match your blood types.

Daratumumab can affect the results of this blood test. These changes can last up to 6 months after your last dose. Your doctor will therefore test your blood type before you start treatment with Daratumumab. The test result will be placed on the patient

identification wallet card you will carry for this study. Please tell all your health care providers that you are using Daratumumab before receiving a blood transfusion.

Risks Associated with Dexamethasone

The most common side effects of dexamethasone that have been seen in humans with multiple myeloma are listed below:

- High blood pressure, retaining water, changes in salt or potassium levels in your body
- Cataracts or glaucoma (with long-term use)
- Bone loss (with long-term use)
- Allergic reaction: Itching or hives, swelling in your face or hands, swelling or tingling in your mouth or throat, chest tightness, trouble breathing
- Changes in vision, trouble seeing, eye pain
- Dark freckles, skin changes, coldness, weakness, tiredness, weight loss
- Depression, unusual thoughts, feelings, or behaviors, trouble sleeping
- Fast or slow, pounding heartbeat
- Fever, chills, cough, sore throat, body aches
- Rapid weight gain, swelling in your hands, ankles, or feet
- Severe stomach pain, nausea, vomiting, or red or black stools
- Trouble breathing
- Trouble urinating
- Worsened joint pain, swelling, or stiffness
- Round, puffy face
- Weight gain around your neck, upper back, breast, face, or waist

Risks Related to Azacitidine

Common, Some May Be Serious (affects more than 20 people in 100 people receiving azacitidine):

- Anemia which may require blood transfusion
- Constipation, diarrhea, nausea, vomiting
- Tiredness, fever
- Swelling and redness at the site of medication injection
- Infection, especially when white blood cell count is low
- Bruising, bleeding
- Loss of appetite
- Shortness of breath
- Rash

Occasional, Some May Be Serious (affects 4 to 20 people in 100 people receiving azacitidine):

- Heart failure which may cause shortness of breath, swelling of ankles, and tiredness
- Fluid around heart
- Abnormal heartbeat
- Swelling and redness of the eye
- Pain
- Heartburn, hemorrhoids
- Difficulty swallowing or sleeping
- Bleeding from multiple sites including the nose
- Internal bleeding which may cause black tarry stool, blood in vomit or coughing up blood
- Sores in mouth
- Chills
- Swelling of arms, legs
- Weight loss
- Muscle weakness
- Dizziness, headache
- Worry, confusion, depression
- Cough, postnasal drip
- Hair loss, itching
- Increased sweating
- Sores on the skin
- Low blood pressure which may cause feeling faint
- Pale skin

Rare, and Serious (affects 3 or fewer people in 100 people receiving azacitidine):

- Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat
- Kidney damage which may cause swelling, may require dialysis

Risks related to Study Procedures

Blood Draws: The risks of drawing blood include temporary discomfort from the needle stick, bruising, and rarely, infection.

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.

Hepatitis B and C Reporting: California regulations require laboratories to report new cases of Hepatitis B, and Hepatitis C infection to the county public health department. The reports include the patient's name, social security number, and other identifying information. Information about these new infections is used to track these diseases statewide and nationwide. Other than this required reporting, your results will be treated confidentially by the study staff. Personally identifying information will not be reported to other departments or agencies.

No radiation risk beyond routine clinical care: This study involves radiation exposure as part of routine clinical care. You will not receive additional radiation as a result of participating in this study. If you have any questions regarding the use of radiation or the risks involved, please consult the physician conducting the study.

Study Drug Combination: The side effects of the combination of daratumumab and azacitidine are not yet known. It is possible that this combination of drugs will cause new or more serious side effects than taking these drugs separately. You will be monitored closely for side effects and your doctor may change your medications if it appears that this combination is causing serious side effects. You should tell your doctor about any side effects you experience while on this study. When additional information about side effects is known, you will be notified of any further study drug related effects.

Infusion Related Risks: As with most intravenous products, you may experience pain, irritation, swelling or bruising, or a slight chance of infection at the site where the intravenous catheter (small tube) is inserted into your vein. These side effects may also be observed at the site where blood is drawn for laboratory tests.

Loss of Privacy: There is a risk of loss of privacy. We will do our best to make sure that your personal information will be kept private. Your samples will be labeled with a code that cannot be used to identify you directly. The list that links your identity to the code on the sample will be kept separate from the samples. The researchers using your samples will never be given your identity.

Reproductive Risks: The effects of daratumumab on fertility, the human embryo, the fetus, or the breast-fed infant are unknown. If you are a woman, taking part in the study might harm your unborn child or breast-fed baby. Thus, you must agree not to become pregnant while you are in this study. Also, you cannot take part in this study if you are pregnant or breastfeeding a child. If you are a man, the effect of daratumumab on your sperm is unknown.

If you are a woman and becoming pregnant is a possibility, you will be required to undergo a pregnancy test prior to taking daratumumab. During the course of the study and for 3 months after the last dose of daratumumab both male and female patients must use effective methods of birth control and not donate sperm/eggs.

The type of birth control you use must be discussed with, and approved by, the study doctor before you begin the study. If you become pregnant or father a child during the study, you must tell the study doctor immediately.

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 the combination of daratumumab, azacitidine, and dexamethasone 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 whether the study drugs could be a treatment for this 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 blood and tissue specimens and information to conduct this study. Once the study is done using your specimens and information, we may 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 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 them 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 of 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.

Genetic Information Nondiscrimination Act (GINA)

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), effective May 21, 2010, generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

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

Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

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 your group. 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 or via phone at,

Swetha Kambhampati, MD
University of California San Francisco
[redacted]

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

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

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 of 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.

California regulations require laboratories to report new cases of hepatitis B, and hepatitis C infection to the county public health department. The reports include the patient's name, social security number, and other identifying information. Information about these new infections is used to track these diseases statewide and nationwide. Other than this required reporting, your results will be treated confidentially by the study staff. Personally identifying information will not be reported to other departments or agencies.

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 Janssen
- Representatives of Multiple Myeloma Research Foundation
- 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?

Janssen Pharmaceuticals will provide funding and daratumumab at no cost to you. Azacitidine will be provided by UCSF. Multiple Myeloma Research Foundation will provide funding for 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.

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 (s), Dr. Swetha Kambhampati or Dr. Alfred Chung, if you feel that you have been injured because of taking part in this study. You can tell the Dr. Kambhampati or Dr. Chung in person or call [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(s) Dr. Swetha Kambhampati [redacted] or Dr. Alfred Chung [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.

OPTIONAL RESEARCH

This section of the informed consent is about additional research studies that are being done with people who are taking part in the study. You may take part in these additional studies only if you want to. Everyone who is receiving study drug is being asked to take part in this optional study.

Optional Blood and Tissue Samples for Future Research

If there is any leftover blood or tissue from the blood draws and tissue biopsies required in this study after the study tests are done, we ask you to donate those left over samples for future research. If you do not want to take part in this optional portion of this study, you may still take part in the main study as described above.

If you agree, your samples and information about you may be made available to others to use for research. 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 them your name, address, phone number, or any other identifiable information. You will not receive any benefit as a result of the tests done on your samples.

Your samples may be helpful for research whether you do or do not have cancer. The research that may be done with your samples is not designed specifically to help you. It might help people who have cancer and other diseases in the future.

Reports about research done with your samples 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 samples 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 samples 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 samples. Then identifiable samples that remains will no longer be used for research.

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

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

Benefits

There will be no direct benefit to you from donating your samples for future research.

The benefits of research using blood and/or tissue include learning more about what causes cancer and other diseases, how to prevent them, and how to treat them. Your samples will be used only for research and will not be sold. The research done with your samples may help to develop new products in the future. New products may have commercial value but you will not receive any compensation for the development or sale of these products.

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.

How will my genetic information be shared?

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. We may give 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 a (public or controlled access) government health research database, but we will not give them your name, address, phone number, or any other identifiable information. Research results from these studies will not be returned to you.

Donating data 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 your group. In some cases, this could reinforce harmful stereotypes.

There will be no direct benefit to you from allowing your 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 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 or by phone, and any remaining data will be destroyed.

However, we cannot retract any data has been shared with other researchers.

Swetha Kambhampati, MD
University of California San Francisco
[redacted]

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

Will I be contacted in the future about this or other research?

We, the local site study team, may want to contact you in the future. You can decide now whether or not you want to be contacted. You can also change your mind later.

If you agree, we may contact you for several reasons. For example, over time, stored samples may be used up or decrease in quality, so we may contact you to ask for more samples. We may also contact you to update basic information or request information about your health.

Additionally, we may want to contact you to see if you want to participate in other research. We will not notify you every time your samples and information are used. However, some researchers might apply to do a study for which they would need to contact you. For example, they might want to ask you to give another sample or to fill

out a survey, or they might ask you to do a phone interview or come in to be seen by a researcher or doctor. If a study like this is approved, someone from this project will contact you. They will tell you about the study so you can decide if you want to receive more information. There will be a new consent process just for that study. You can decide then to take part or not take part. If at any time you decide you no longer want to be contacted about future studies, please tell us.

Can I change my mind after I agree to let my samples be used?

You have the right to change your mind about the future use of your leftover blood and tissue samples and information at any time. If you want to leave the project, let us know. Just contact the study doctors, Swetha Kambhampati, MD, or Alfred Chung, MD in writing or by phone and let us know that you do not want us to keep your samples.

Making Your Choice

Please read each sentence below and think about your choice. After reading each 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 Institutional Review Board at 415-476-1814.

No matter what you decide to do, it will not affect your care.

1. **My excess tissue may be kept for use in research to learn about, prevent, or treat cancer and other diseases.**

YES	NO

2. **My excess blood may be kept for use in research to learn about, prevent, or treat cancer and other diseases.**

YES	NO

3. **Someone may contact me in the future to ask me to take part in more 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
Date	Person Obtaining Consent
	Person Obtaining Consent Name (Printed)
Date	Witness – Only required if the participant is a non-English speaker
	Witness's Name (Printed) – Only required if the participant is a non-English speaker

AND/OR:

Date	Legally Authorized Representative
	Legally Authorized Representative Name (Printed)

Date

Person Obtaining Consent

Person Obtaining Consent Name (Printed)