

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

### **Study Title: CC# 16704 Testing the ability of Pembrolizumab to alter the Tumor Immune MicroEnvironment (TIME) of high risk DCIS**

This is a clinical trial, a type of research study. Your study doctors, Dr. Laura Esserman, MD, MBA, and Dr. Jasmine Wong, MD, from the UCSF Helen Diller Family Comprehensive Cancer Center will explain the clinical trial to you.

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

You are being asked to take part in this study because you have been diagnosed with high risk, ductal carcinoma in situ (DCIS).

### **Why is this study being done?**

The purpose of this study is to find out what effects, good and/or bad, pembrolizumab has on you and your high risk DCIS. In addition, the investigators want to find out whether intralesional injection (an injection using a needle under ultrasound guidance into your tumor in the area of your biopsy clip) with pembrolizumab can make the environment around your tumor different by changing how your body's immune system responds.

Pembrolizumab is an antibody (a protein produced by the body's immune system) that is designed to bind to and block the activity of PD-1, a molecule in your body that may be responsible for inhibiting your body's immune response against your cancer cells.

Pembrolizumab has been approved for treatment of certain types of adult melanoma and non-small cell lung cancer by the US Food and Drug Administration (FDA) however it has not been approved to treat high risk DCIS. The use of pembrolizumab in this study is an investigational use of the drug.

Merck Sharp & Dohme Corp. (a subsidiary of Merck & Co., Inc.) is providing funding to UCSF to conduct the study. Merck will also provide pembrolizumab at no cost to study participants.

### **How many people will take part in this study?**

A total of approximately 39 patients will take part in this study.

At the beginning of the study, 9 patients were treated with a various doses of the drug, called the dose escalation phase. Even at higher dosages of the drug, patients did not experience any bad side effects. You can ask your study doctor about that part of the study which already occurred.

The next phase of the study is called the dose expansion phase in which we will enroll a total of 30 patients.

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

The study doctor will let you know what phase of the trial you will participate in once you consent to be a part of this study and you meet the study's eligibility criteria.

### **Dose Escalation Cohort**

Patients were assigned to a group with a specific dosage, the study drug (pembrolizumab) was injected into patient's tumor (intralesional injection) on 2 occasions that were 3 weeks apart. Once the patient finished receiving the 2 doses of pembrolizumab, she had surgery 3 weeks after the 2<sup>nd</sup> dose of pembrolizumab as part of routine cancer care. The patient and her surgeon discussed the options of a partial mastectomy or a mastectomy. After surgery, the patient was asked to come back to the clinic for follow-up exams and procedures detailed below.

### **Dose Expansion Cohort**

The safety results of intralesional injection pembrolizumab from dose escalation did not reveal any safety risks. In the dose expansion cohort, 20 patients will be treated with the study drug on 4 occasions that are 3 weeks apart and then have surgery at 3 weeks after the 4<sup>th</sup> dose of pembrolizumab as part of routine cancer care. In addition, 10 patients can elect to be on the control arm, in which case you will follow the standard of care. For both treatment and control patients, you and your surgeon will discuss whether you will have a partial mastectomy or a mastectomy. After surgery, you will be asked to come back to the clinic for follow-up exams and procedures detailed below.

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

You will need to have the following exams, tests or procedures to find out if you are eligible. These exams, tests, or procedures are part of routine 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.

All procedures must be done within 28 days prior to the start of the treatment, unless otherwise noted.

### **Screening**

*This visit will take about 4-5 hours to complete.*

The following procedures and assessments will be done during both phases of the study unless otherwise indicated:

- Ask you about your health and medical history
- Conduct a complete physical exam
- Measure vital signs (blood pressure, temperature, pulse, breathing rate, and oxygen saturation) including weight and height
- Ask you how well you can do the regular activities of daily life (called *performance status*)

- Ask about any medications (including previous cancer treatments) you have been taking (called *concomitant medication*)
- Magnetic Resonance Imaging (MRI) Scan of the breast before being randomized in the dose expansion cohort.
  - An **MRI scan** takes an image of your 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.
- Collect urine samples to check for safety factors including urine pregnancy test. Results need to be within 3 day prior to beginning study treatment.
- Collect blood samples (about 2 tablespoons) for:
  1. Routine safety tests
    - Measuring the chemical parts of your blood (called *biochemistry*)
    - Counting the number of white and red blood cells and platelets (called *hematology*)
  2. Pregnancy test, if you are a woman of childbearing potential and the urine pregnancy test cannot confirm a negative result. Results need to be within 3 days prior to beginning study treatment.
  3. Seeing how well your blood clots (called *coagulation*)
  4. Seeing how well your thyroid is working (called *thyroid function test*)
  5. Research

### **During the main part of the study...**

For this study, the visits are organized in 3-week intervals. You will visit the clinic on Day 1 of this 3-week cycle to receive an intralesional injection of pembrolizumab. After the 4<sup>th</sup> intralesional injection of pembrolizumab, you will receive surgical treatment as part of routine cancer care. For patients on the control arm of the expansion cohort, you will only receive surgical treatment as part of routine cancer care.

### **Day 1 of 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, and 4<sup>th</sup> dose**

*These visits will take approximately 2 hours to complete.*

The following procedures and assessments will be done during both phases of the study unless otherwise indicated:

- Conduct a directed physical exam instead of a full physical exam to more closely examine a focused area of concern.

- Measure vital signs (blood pressure, temperature, pulse, breathing rate, and oxygen saturation) including weight
- Ask about your performance status
- Ask about any concomitant medications you have been taking
- Ask about any side effects you are having before receiving study treatment
- Receive an intralesional injection of pembrolizumab
  - In this procedure, the surgeon in the clinic will use ultrasound imaging and use the visible clips that were placed at your initial biopsy to guide the placement of the single injection. If the clips were not used at your initial biopsy, the surgeon may work with a radiologist to use a mammography scan to place the clips and perform the injection.
- Collect urine samples to check for safety factors including urine pregnancy test.
- Collect blood samples (about 2 tablespoons).
  1. Routine safety tests
  2. Pregnancy test, if you are a woman of childbearing potential and the urine pregnancy test cannot confirm a negative result. Results need to be within 3 days prior to beginning study treatment.
  3. Coagulation test
  4. Thyroid function test
  5. Research

### **End-of-Treatment Visit**

Approximately 3 weeks after your 4<sup>th</sup> dose of intralesional injection of pembrolizumab, you will have surgery determined by you and your doctor to have either a partial mastectomy or a mastectomy, as part of routine cancer care.

The following procedures and assessments will be done during both phases of the study unless otherwise indicated:

- Conduct a directed physical exam
- Measure vital signs (blood pressure, temperature, pulse, breathing rate, and oxygen saturation) including weight.
- Ask about your performance status
- Ask about any concomitant medications you have been taking
- Ask about any side effects you are having before receiving study treatment
- Undergo surgery to remove your DCIS. The type of surgical treatment (partial mastectomy vs. mastectomy) will be discussed between you and the surgeon prior to this surgical procedure.
  - The tissue from this surgical procedure will be compared with your prior tissue biopsy and compared to help understand your body's local immune response in your tumor after short term exposure to pembrolizumab.
- MRI scan of the breast before surgery (only during dose expansion)

### **Safety Follow-up/Post-Op Visit**

You will be asked to return to the clinic for a safety follow-up approximately 1-3 weeks after your surgery to perform final tests to ensure your safety as part of your routine cancer care.

The following procedures and assessments will be done during both phases of the study unless otherwise indicated:

- Conduct a directed physical exam
- Measure vital signs (blood pressure, temperature, pulse, breathing rate, and oxygen saturation) including weight
- Ask about your performance status
- Ask about any concomitant medications you have been taking
- Ask about any side effects from receiving study treatment
- Collect urine samples to check for safety factors
- Collect blood samples (about 2 tablespoons) for:
  1. Routine safety tests
  2. Coagulation test
  3. Thyroid function test
  4. Research tube

### **Follow-up Visit**

The total duration of this study is approximately 8-15 weeks in the dose expansion cohort. Given the relatively short period of this study, any toxicity from the study will be followed 8 weeks after your surgical treatment.

The following procedures and assessments will be done:

- Conduct a directed physical exam
- Measure vital signs (blood pressure, temperature, pulse, breathing rate, and oxygen saturation) including weight
- Ask about your performance status
- Ask about any concomitant medications you have been taking
- Ask about any side effects from receiving study treatment

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

### **HOW LONG WILL I BE IN THE STUDY?**

The total duration of the trial is about 8-15 weeks, so long as you do not have severe side effects or decide to withdraw your consent to participate in this study or the study is closed.

How long you are in this study depends on many things. However, you can be in the study for a longer or shorter time. How long you will be in this study depends on how you respond to the study drug treatment, how long you are able to safely be treated without significant side effects and by how long you and the study doctor determines that you are gaining clinical benefit, and by how long you are willing to take part in this study.

You can be in the study until any of the following happens:

- You decide you want to stop receiving the study drug
- You experience side effects from the study drug that you find unacceptable
- You need a health treatment not allowed in this study
- The sponsor decides to stop the study
- You have unexpected events that affect your health and safety
- The study doctor thinks it is in your best interest to stop being in the study\

## **CAN I STOP BEING IN THE STUDY?**

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

It is important to tell the study doctor if you are thinking about stopping so any risks from 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 he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

## **WHAT IS KNOWN ABOUT THE STUDY DRUG?**

Pembrolizumab, which is approved in the USA and some other countries, is available by prescription to treat several different cancers, but may not be approved to treat your type of cancer.

Overall, as of 03-Mar-2018, approximately 25,519 patients have been treated with pembrolizumab in clinical studies.

Pembrolizumab works by helping your immune system to fight your cancer. Pembrolizumab is approved and is available by prescription to treat a type of skin cancer called malignant melanoma.

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.

## **What side effects could the study drug cause?**

You might experience some or all of these same side effects. However given the very small intralesional dose you are receiving compared to the approved FDA dose, the chance of a significant systemic side effect is very low. It is also possible that you might experience side effects that are unknown at this time. As is true for any experimental drug, there may be unknown and potentially serious or life-threatening side effects that could occur with pembrolizumab.

### **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
- Low levels of salt in the blood that may cause you to feel tired, confused, have a headache, muscle cramps and/or feel sick to your stomach

### **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
- Too much thyroid hormone so you may feel anxious, angry, have trouble sleeping, feel weak, tremble, sweat, feel tired, have loose and watery stools
- Infusion reaction, where you may feel dizzy or faint, flushed, get a rash, have a fever, feel short of breath at the time of receiving your infusion (IV) or just after, or 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
- 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

### **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
- Inflammation of the muscles so you may feel weak or have pain in your muscles
- 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 vomiting that gets worse when you eat
- Inflammation of the eye so you may have eye redness, blurred vision, sensitivity to light, eye pain, see floaters or have headaches
- 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

### **Other Risks Related to Study Procedures**

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

**Intralesional Injection risks:** Injection of study drug into the site of your tumor may cause temporary discomfort, bruising, and a local skin reaction. There may also be a small chance of a skin infection at the injection site.

### **Scan Procedures:**

- **Mammogram risks:** This research study involves exposure to radiation from mammography if deemed necessary by your study doctor. This radiation exposure is not necessary for your medical care and is for research purposes only. The additional amount of radiation that you will receive as a result of participating in this study will be less than the yearly natural background radiation in the US, which is 3 mSv (a mSv, or milliSievert, is a measurement of radiation). This amount of radiation involves minimal risk. If you are pregnant, you SHOULD NOT participate in this study. If you have any questions regarding the use of radiation or the risks involved, please consult the physician conducting the study.
- **MRI risks:** Because the MRI machine acts like a large magnet, it could move iron-containing objects in the MRI room during your examination, which in the process could possibly harm you. Precautions have been taken to prevent such an event from happening; loose metal objects, like pocket knives or key chains are not allowed in the MRI room. If you have a piece of metal in your body, such as a fragment in your eye, aneurysm clips, ear implants, spinal nerve stimulators, or a pacemaker, you will not be allowed into the MRI room and cannot have an MRI.

Having an MRI may mean some added discomfort for you. In particular, you may be bothered by feelings of claustrophobia and by the loud banging noise during the study. Temporary hearing loss has been reported from this loud noise. This is why you will be asked to wear earplugs. At times during the test, you may be asked to not swallow for a while, which can be uncomfortable.



Because the risks to a fetus from MRI are unknown, pregnant women must not participate in this study.

**Contrast agent (gadolinium) risks:** A few side effects of gadolinium injection such as mild headache, nausea, and local pain may occur. Rarely (less than 1% of the time) low blood pressure and lightheadedness occurs. This can be treated immediately with intravenous fluids. Very rarely (less than one in one thousand), patients are allergic to gadolinium. These effects are most commonly hives and itchy eyes, but more severe reactions have been seen which result in shortness of breath.

Patients with severe kidney disease sometimes have a bad reaction to gadolinium contrast. The condition is called nephrogenic systemic fibrosis (NSF). It can cause skin to tighten or scar and can damage internal organs. Sometimes it can be life-threatening. There are no reports of NSF in patients with normal kidney function. Before you have a MRI scan requiring an injection of gadolinium contrast, you will have a blood test in order to check the function of your kidneys. Based on your medical history and the results of the test, a doctor will decide whether it is safe for you to undergo the MRI scans.

**Ultrasound risk:** There is a risk that you may experience an allergic reaction to the gel-like substance used during this procedure. There may be some discomfort from the pressure of the device that is used to make the sound waves as it is pressed up against your body.

**Reproductive risks:** It is not known if the study drug may affect an unborn or nursing baby. Chemotherapy can cause harm to an unborn child. If you are pregnant, trying to become pregnant or breast-feeding, you may not be in the study. The study doctor will perform a blood or urine pregnancy test before the start of and during the study, if you are able to have a baby.

If you are able to have a baby, you must avoid having sex (abstinence) or use reliable birth control methods during the study and for a period of 4 months after your last dose of pembrolizumab (Keytruda). The following birth control methods are allowed during the study as per local regulations or guidelines:

Two (2) of the following barrier methods in combination:

- Diaphragm
- Condom
- Copper intrauterine device (IUD)
- Contraceptive sponge
- Spermicide

OR

One (1) of the above barrier methods in combination with:

- Hormonal contraceptives (including oral, subcutaneous, intrauterine, or intramuscular) that are registered and marketed containing estrogen and/or a progestational agent

If you become pregnant during the study you must notify the study doctor right away. The study drug will be stopped and you may be taken out of the study.

**Privacy Risks:** 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. The chance that your personal information will be given to someone else is very small.

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

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

## **ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**

Taking part in this study may or may not make your health better. While doctors hope the study treatment will be more useful against cancer compared to the usual treatment, there is no proof of this. Your cancer may not get better, or it may even get worse while you are participating in this study. We do know that the information from this study will help doctors learn more about the study drug 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 surgical treatment (partial mastectomy or mastectomy) for your tumor without being in a study
- Taking part in another study
- Getting no treatment

Your physician will discuss these other options with you. Please talk to your doctor about your choices before deciding if you will take part in this study.

## **WILL MY MEDICAL INFORMATION BE KEPT PRIVATE?**

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 but will not 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. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The University of California
- Merck
- The National Cancer Institute (NCI) and other government agencies, e.g., the Food and Drug Administration (FDA), involved in overseeing research

## **WHAT ARE THE COSTS OF TAKING PART IN THE STUDY?**

Some of the services you will receive are being done only because you are participating in this research study. Examples of these ‘research only’ services include: supply of study drug, , MRI imaging during the expansion phase, and review of side effects related to the drug. Those services will be paid for by the study and will not be billed to you or your health insurance company. If you believe you have received a bill for a research related procedure contact the study team and the UCSF Medical Center office that sent the bill.

In addition, some of the services you will receive during this research study are considered to be “routine cancer care” that you would have received even if you were not participating in the research study. Examples include a mammogram for clip placement, administration of intralesional injection of the study drug, including any medically necessary MRI or ultrasound imaging to guide the needle. These services will be billed to your health insurance company, and you will be responsible for paying any deductibles, co-payments or co-insurance that are a normal part of your health insurance plan. If you do not have health insurance, you will be responsible for those costs.

Before you agree to be in this study, you may want to contact your healthcare payer/insurer to see if your plan will cover the costs required as part of your participation. You may request more information about the costs of participating in this study and discuss this with the study team.

If you have any questions, your doctor and the study team will be able to provide you with answers.

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

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

## **WILL I BE PAID FOR TAKING PART IN THIS STUDY?**

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

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

It is important that you tell the study doctors, Dr. Laura Esserman, MD, MBA, and Dr. Jasmine Wong, MD, or one of their associate if you feel that you have been injured because of taking part in this study. You can tell them in-person or call them at 415-353-7070.

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

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

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

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

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

## **WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?**

You can talk to the study doctors about any questions, concerns, or complaints you have about this study. Contact your study doctors, Dr. Laura Esserman, MD, MBA, and Dr. Jasmine Wong, MD, or one of their associates at 415-353-7070.

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

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, 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.

## **SERVING AS A CONTROL**

If you are eligible to participate in the study but do not want to receive the therapeutic agent, you have the option to serve as a control. Your participation as a control in this study will give us information about whether the intralesional injection of pembrolizumab activates an immune response in women with DCIS. We will compare the changes in the immune landscapes of DCIS in women treated with pembrolizumab to the immune landscape of your untreated DCIS. The information gained from this study will help doctors and scientists learn more about DCIS, and this may benefit patients in the future.

We will collect a breast tissue sample only if you and your doctor elect surgery as part of your treatment plan. The surgery will be a standard of care procedure; you will **not** be required to have surgery as a part of this research study. Instead of discarding your leftover biological sample surgery, we will save a small amount of breast tissue in what is called a “Tissue Bank.” We will also request to use tissue from your diagnostic biopsy. We will use this tissue to characterize the immune landscape of your DCIS. You will also be asked to provide a blood sample before and after your surgery for research purposes.

Your specimens may be kept indefinitely at UCSF. Your specimens will be coded using a unique study ID. They are only being stored for the purpose of the study and will not be shared with other researchers. If you decide later that you do not want your specimens and information to be used for research, you can notify the investigator in writing at:

Laura Esserman, MD, MBA  
University of California, San Francisco  
1600 Divisadero Street, Box 1710  
San Francisco, CA 94115

And we will not use your blood, tissue specimens, and health information in any future research. Please let Dr. Esserman know if you would like any remaining identifiable tissue specimens destroyed if they are no longer needed for your care. However, if any research has already been done using portions of your specimens and health information, the data will be kept and analyzed as a part of those research studies.

There will be no additional risk due to the removal of breast tissue for the Tissue Bank. You will receive care appropriate for recovery from the surgical procedure.

Please read the sentence below and think about your choices. After reaching each sentence, put your initials in the “Yes” or “No” Box and write the date. If you have any questions, please talk to your doctor, or nurse, or call our research review board at 415-476-1814

1. I do not wish to receive the therapeutic agent; however I am willing to serve as a control by donating my tissue for research purposes.

<i>YES</i>	<i>NO</i>
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**CONSENT**

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

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

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

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

\_\_\_\_\_  
Date

\_\_\_\_\_  
Participant's Signature for Consent

\_\_\_\_\_  
Printed Name of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Printed Name of Person Obtaining Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness Signature (Only required if the participant is a non-English speaker)