NCT# 02435472

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

A Randomized Clinical Trial of Exercise versus Usual Care among Men Opting for Active Surveillance for Prostate Cancer (AS Exercise RCT)

This is a clinical trial, a type of research study. Your study doctor(s), June Chan, ScD Matthew R. Cooperberg, MD, MPH, Anthony Luke, MD, and Peter Carroll, MD, MPH and associates from the UCSF Departments of Epidemiology & Biostatistics and Urology and Department of Orthopedic Surgery 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 early stage prostate cancer and have elected Active Surveillance as your primary management approach.

Why is this study being done?

It is currently not known whether exercise after prostate cancer diagnosis is associated with changes in prostate cancer biology or changes in the risk of prostate cancer progression. This study is designed to find out if aerobic exercise changes prostate cancer biology in men undergoing active surveillance.

The National Institutes of Health (NIH) / National Cancer Institute provides financial support for the conduct of this study.

How many people will take part in this study?

About 100 men will take part in this portion of the study (RCT) for a total of 200 men for overall study target (including 70 in Non-Randomized Cohort Group, and 30 in Non Randomized Control Group).

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

If you agree to be in this study, you will be asked to sign and date the informed consent form, you will complete the following tests and procedures to make sure that you are eligible for study participation.

Before you begin the study...
You will need to have the following exams, tests or procedures to find out if you can be in the study. Some of these exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. *If you have had some of them recently, they may not need to be repeated.* This will be up to your study doctor.

You will have the following routine baseline exams

- Physical Assessment (weight, height, heart rate, blood pressure, waist and hip circumference measures.)
- Donation of tissue from prior standard of care biopsy – we will request a sample from the leftover residual tissue from a biopsy that you had before starting this study. This will be analyzed for research purposes.

You will have the following research baseline exams:

- **Fasting Research Blood Draw (approximately 15minutes)**
  The purpose of this blood draw is to examine how specific markers in the blood may be modified by aerobic training. We will draw approximately 8 tablespoons (100-120 ml) of blood for this purpose. This blood will be stored and tested at a later point. Blood will be collected after a minimum of 8 hour water-only fast. You may take your normal daily medications. We will ask you to bring a light snack that you are used to eating for after your blood draw (if you forget, we will have light snack options on-hand).
- Urine collection for research (~ 5 min)
  We will request a urine sample for research purposes.

- **Supervised Exercise (Fitness) Test (~45 minute appointment with the test lasting 8-15 minutes)**

To ensure that it is safe for you to participate in this study, a supervised exercise (fitness) test will be performed. It is not part of usual cancer care. This test will take place at the Human Performance Center at the Mission Bay UCSF campus site, after the blood draw. An exercise physiologist and the medical staff of the Human Performance Center will be monitoring your test and available in the event of an emergency.

The exercise test will be performed on a treadmill, and the grade (slope) or speed is increased every 1-2 minutes. The test is stopped when you reach your body's maximal oxygen consumption (this occurs when you are exerting your maximal effort on the treadmill). Once you reach this level, the test is immediately stopped, so you will not be in discomfort for very long. The test will last 8- 15 minutes. You can stop the test at any time. If you prefer, a cycling-based test may be used instead, based on your request and an assessment by the exercise team.

To accurately measure your fitness level, we will measure all of the oxygen and carbon dioxide that go into and out of your mouth during the exercise test. We do this by asking you to wear either a mouthpiece (similar to a snorkel used in deep sea diving) or a fitted mask that covers your nose and mouth, which is connected to a tube that transports all gases into a machine (called a metabolic cart) where it is analyzed. If you use the mouthpiece, you will be asked to wear a nose clip, and breathe only in and out of your mouth during the test.

The exercise test will last approximately 8 to 15 minutes. You may be asked to perform this test twice at baseline to help familiarize you with the test procedures and equipment. As a safety precaution, during the test, we will monitor the electrical activity of your heart using a 12-lead ECG. Twelve ECG electrodes (sticky pads) will be placed at specific locations on your torso so that we can monitor the response of your heart to exercise. As necessary, we may need to shave off your hair (using a safety razor) in the areas where the sticky pads are attached to attain a secure connection (this is standard of care when using an ECG).

- **Lifestyle (including diet & exercise) and Quality of Life Questionnaires (approximately 60-90 minutes for the questionnaires)**

We want to know your views on how your life has been affected by cancer and being on active surveillance. This survey data looks at how you are feeling physically and emotionally during your cancer management. It also looks at how you are able to carry out your day-to-day activities. We will also ask about your exercise and dietary habits via questionnaire. This information will help doctors better understand how patients feel and what they do during active surveillance. In the future, this information may help patients and doctors as they decide which management options to use for prostate cancer.

You will also be asked to repeat these assessments at the end of the intervention period (16 weeks), as well as 12-months and 24-months after you enroll.

If any questions make you feel uncomfortable, you may skip those questions and not give an answer.

During the study...
If the exams, tests and procedures show that you can be in the randomized clinical trial, and you choose to take part, then you will undergo the following tests and procedures.

Following the successful completion of all of the initial (baseline) exams and questionnaires (as described above), you will be randomized into one of the study groups described below.

Randomization means that you are put into one or the other group by chance. A computer program will place you in one of the groups. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in either group.

(1) Aerobic Training Group: You will be given print materials describing the benefits of exercise for men with prostate cancer. You will also participate in an individually-tailored aerobic exercise training program for ~4 months (16 weeks). The exercise program is intended to increase your cardiopulmonary fitness, gradually and safely; and will be tailored to your baseline exercise assessments (maximal oxygen capacity, VO_{2max} and corresponding heart rate). We will ask you to exercise with specific heart rate goals for each session. The exercise program will follow American College of Sports Medicine guidelines and is designed to safely and gradually increase your cardiopulmonary fitness, which is generally achieved by increasing intensity, duration, or frequency of exercise. The

exercise program will consist of ~ three to five aerobic exercise sessions per week, which you will be asked to do on your own, either outdoors, at home, or at a gym.

At the beginning of the 16 weeks, we will ask you to attend one orientation exercise session at the UCSF Bakar Fitness Center with an exercise physiologist. At this visit, s/he will provide you with individual exercise counseling, & orient you on how to use an objective heart rate monitoring device (e.g., watch or chest-strap), how to read and follow your training program, and observe you exercising to give advice on how to reach the provided heart rate goals. The exercise physiologist will develop a specific plan for you, based on your assessments and activity preferences. You will be asked to wear the monitoring device that tracks heart rate and other physical activity variables (e.g., steps taken, minutes active) during all your exercise sessions; and we will ask for your permission to access these data remotely throughout the study. We will also ask brief questions about your readiness to exercise, Perceived Exertion, and how the workout went, after each exercise session online or on paper. If you have access to a smart phone, you may receive instructions on how to use a phone-based app to support your training goals. We will provide you with individualized
weekly exercise counseling call in the form of a phone call (approximately 15-20 min/call).

During these calls, the exercise physiologist/trainer will:

1) inquire about how you are doing & the status of your weekly exercise sessions;
2) collect or review a few data points about your exercise sessions;
3) provide advice for your next exercise sessions,
4) answer any questions you may have about the exercise program, heart rate monitor, how to exercise safely, etc. and
5) discuss how we can further support your exercise plans.

If we notice that you are not wearing the heart rate monitoring device, or not meeting each session's heart rate or duration goals, we may contact you up to 2 additional times/week during the 16 weeks (i.e., maximum number of contacts initiated by us = 3 times/week for 16 weeks). If at any time we have questions or concerns about your safety (based on reviewing the remote heart rate or exercise data), we may call you. If you have questions at any time, you may call us. After the final study- related visit (in Week 16-18), you will be provided with one final session with the exercise physiologist and an individualized aerobic exercise program for future use, re-tailored based on your 16 week fitness evaluation.

OR

(2) Usual Care Group: You will be given print materials describing the benefits of exercise for men with prostate cancer. After the final study-related visit (in Week 16-18), you will have one free session with an exercise physiologist and receive an individualized aerobic exercise program based on your exercise test results. You will be asked to maintain your usual diet and exercise habits during the 16-week study.

If the exams, tests, or procedures indicate that you are ineligible to proceed to the randomized clinical trial, we would like to use your completed baseline assessments and biospecimens for research, and follow your prostate cancer status through questionnaires and medical record abstraction. We would also ask you to complete the lifestyle and quality-of-life questionnaires at 12 and 24 months. If we are unable to obtain current

medical records, we may contact you briefly to update our records.

In addition to these groups, we also offer this study to men without diagnosis of prostate cancer. We call this group: C-Control group. About 50 patients will be enrolled in this group C.

When I am finished with my aerobic training or usual care program

At the end of the study intervention period (approximately 16 weeks) you will be asked to repeat the same exams, tests, and procedures that were performed before you entered the study. These tests are listed below (the full description of each assessment was provided above). These tests are for research purposes only and are not considered part of your standard cancer care.

- Lifestyle and Quality of Life Questionnaire (completed prior to final studyvisit)
- Research Blood Draw
- Research Urine Collection
- Supervised Exercise (Fitness) Test

In addition, you will be scheduled to undergo a trans-urethral ultrasound-guided prostate biopsy as part of your active surveillance management. This biopsy will take place after completing the 16- week study. We will request a sample from the leftover residual tissue from this biopsy to be analyzed for research purposes.

Following the completion of these assessments and procedures the main portion of your participation in this study will be completed. An overview of the type and timing of tests and procedures are provided below.

Assessments	Tests Before the Study (week 0)	Tests After the Study (Week 17 +/- 2 weeks)
Exercise (Fitness) Test (includes heart rate, blood pressure, and weight assessment)	**X**	**X**
Clinical Visit Assessment (includes weight, height, waist/hip circmference, heart rate, blood pressure, PSA [1]	**X**	**X**
Fasting research blood draw	**X**	**X**
Urine Collection	**X**	**X**
Lifestyle and Quality of Life Questionnaire	**X**	**X**
Transrectal Ultrasound-Guided Biopsy	**X[2]**	**X[2]**
Exercise Counseling (intervention group only) via Calls or Emails	**1-3 times/week for 16 weeks**	
Follow-up contact (phone, emails, or paper)	**X**	**X**

[1]PSA tests may be monitored quarterly, per standard of care for active surveillance.

[2] We will request leftover tissue samples from two standard of care biopsies, one that occurred prior to randomization, and one from after the 16-week intervention, as part of usual active surveillance management. Samples collected from a biopsy conducted beyond two-week period is acceptable. Samples will be analyzed for research.

What will happen if I agree to donate biospecimens for this study?

Sometimes specimens are used for genetic research (about diseases that are passed on in families). Even if your tissue or blood is used for this kind of research, the results will not be put in your health records. Reports about research done with your tissue or blood will not be given to you or your doctor. The research will not have an effect on your care.

Genetic information (also known as genotype data) and the medical record data (also known as phenotype data) may be shared broadly in a coded anonymous form for future genetic research or analysis. We may give certain medical information about you (for example, age, characteristics about your cancer diagnosis and management, and vital status) to other scientists or companies not at UCSF, including to a controlled access government health research database, but we will not give them your name, address, phone number, or any other identifiable information.

Your specimens will be kept indefinitely. If you decide later that you do not want your information to be used for future research, you can notify the investigator in writing at Dr. June Chan, ScD, care of Imelda Tenggara via email at Imelda.tenggara@ucsf.edu, and any remaining identifiable specimens and information will be destroyed if they are no longer needed for your care. We can return any unused tissue. However, if any research has already been done using portions of your specimens, the data will be kept and analyzed as part of those research studies.

Study locations:
The exercise testing will take place at the UCSF Human Performance Center (Mission Bay campus). The blood draw will take place at UCSF Urology Outpatient Clinic, UCSF Clinical Lab, or the UCSF Human Performance Center/Orthopedics Institute. If you are randomized to the Aerobic Training group, the one Orientation Exercise Session will take place at the UCSF Bakar Fitness Center (Mission Bay campus) or the Millberry Fitness and Recreation Center (Parnassus campus), or the UCSF Human Performance Center/Orthopedics Institute.

How long will I be in the study?

The study intervention (i.e., aerobic training or the usual care group) will last for approximately 16 weeks. After the completion of these 16 weeks, we will follow your disease status and management for 2 years. We will ask you to complete questionnaires about your quality of life and lifestyle habits at 12 months and 2 years (online or on paper; you may indicate your preference for completing these surveys). We would also like to keep track of your medical condition for the rest of your life. We would like to do this through medical

record review and by calling you on the telephone or sending you an email or print survey once a year to see how you are doing (you may indicate how you prefer to be contacted). Keeping in touch with you and checking on your condition every year helps us look at the long-term effects of 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 the aerobic exercise can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

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

What side effects or risks can I expect from being in the study?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Many side effects go away soon after you stop participating in the aerobic exercise program. In some cases, side effects can be serious, long lasting, or may never go away.

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

Risks and side effects related to the study include those which are:

- **Less Likely** Blood Collection (both groups) – There are some minor risks associated with a blood draw (i.e., bruising, discomfort, light-headedness and in some rare occasions nerve damage). However, this procedure is considered to be of minimal risk and will be performed by trained staff at the UCSF Helen Diller Family Comprehensive Cancer Center, UCSF blood labs, or UCSF Human Performance Center/Orthopedics Institute.
- **Likely (aerobic training group only) -** The aerobic exercise program may cause general tiredness, muscle fatigue or soreness, joint pain, lower back pain, or leg cramps. You may also experience shortness of breath while exercising.

- **Rare but serious** Cardiopulmonary Exercise Testing (both groups) – Graded exercise testing may cause or reveal that you are at risk for an adverse cardiovascular event. These events are rare (about <1/100,000 in well individuals and 1/10,000 in sick individuals). A trained health professional (e.g. medical staff and exercise physiologist) will monitor you during the exercise test in a location staffed by physicians, in the rare event that you experience such an event.

- **Rare but serious** Home-Based Aerobic Training (aerobic training group only) – Similar to cardiopulmonary exercise testing, exercise training may cause temporary risks of an adverse cardiovascular event, such as a heart attack. The full echocardiogram, professionally-monitored graded exercise test that you must complete *prior* to exercise training will help us determine whether your heart is healthy enough to engage in exercise training, and if it is not, then you will not be eligible to participate in this study. If assigned to the intervention group, you will be asked to exercise ~3-5/week, with the goal of having your heart rate at a specific level, relative to your own assessed fitness and which is recommended by the American College of Sports Medicine. You will be provided with an in-person orientation session on how to follow your tailored exercise program, including guidance on how to exercise safely.

- **Randomization risks:** You will be randomly assigned to an exercise intervention program by chance. Aerobic exercise training may be less effective at managing your cancer and symptoms and may have more side effects than your typical exercise habits under standard care.
- **Unknown Risks:** The experimental exercise program 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.

- Genetic information that results from this study does not have medical or treatment importance at this time. However, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health. To further safeguard your privacy, genetic information obtained in this study will not be placed in your medical record.

- Taking part in a genetic study may also have a negative impact or unintended consequences on family or other relationships. If you do not share information about taking part in this study, you will reduce this risk. Although your name will not be with the sample, it will have other facts about you such as your diagnosis. 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.

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

  If you are interested in this study, we encourage you to consult with your primary care physician to confirm that the aerobic exercise is appropriate for you.

Are there benefits to taking part in the study?

Taking part in this study may or may not make your health better. While doctors hypothesize that an aerobic exercise program may have beneficial effects on prostate biology and improve your well-being compared to active surveillance alone, there is no proof of this. We do know that the information from this study will help doctors learn more about the benefit of the aerobic exercise program as a complementary management strategy for prostate cancer. This information could help future cancer patients. Additionally, it is well established that participation in regular physical activity improves cardiovascular health and reduces risk

of overall death.

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, including prostate cancer. In some instances, data or any new products, tests or discoveries that result from this research may have potential commercial value. You will not share in any financial benefits. Your personal health information cannot be used for additional research without approval from either you or a review committee.

What other choices do I have if I do not take part in this study?

Your other choices may include:

- Taking part in another study.
- Continuing an Active Surveillance regime without being in a study.
- Receiving treatment

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

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 but will not be added to your medical record. Data from your medical record will be stored in the Urology Outcomes Database (UODB), (an electronic database which supports clinical care, CHR #11-05329) and may be used for clinical research. If you consent to this study, your decision will imply consenting to be included in the Urology Outcomes Database. 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, and information from the study will be presented at the group (not individual) level.

Donating data or 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. Your name will not be used in any published reports from research performed using your specimen. Select tissue bank staff members will have access to information about you but will not release any identifying information about you to researchers using your specimen. The UCSF Institutional Review Board and other University of California personnel also may see information about you to check on the tissue bank.

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

- The University of California
- The National Cancer Institute (NCI)

What are the costs of taking part in this study?

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

You and/or your health plan WILL be charged for:

- Routine/standard of care doctor visits with your oncologist
- Routine/standard of care imaging and scans
- Routine/standard of care blood tests
- Standard of care biopsy

You and/or your health plan WILL NOT be charged for:

- Exercise (Fitness) Tests
- Fasting Research blood draws
- Urine collection
- Assessment of weight, height, heart rate, and hip/waist circumference at baseline and follow up clinic visit
- Study questionnaires
- Provision of aerobic exercise plan and counseling for men assigned to the intervention group
- Parking costs associated with attending the baseline and follow-up clinic visit for both groups; parking associated with attending the baseline orientation exercise session for the aerobic training group.

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 be paid up to $500 (in the form of a gift card e.g., Amazon or Visa gift card) for taking part in this study. You will receive $100 for the completion of the baseline assessment and another $400 for the completion of the full 16-week study and end of study assessment

(Week 16-18). You will also be provided with a detailed brochure (e.g. 40 pages) on exercise for cancer survivors (both groups). All men will be offered one free session with the exercise physiologist after the final study visit in Week 16-18 during which they will develop an individualized aerobic exercise program for future use, based on their most recent fitness evaluation. Men will also be offered a personalized lifestyle report with guidance on ways to reduce cancer progression, at the end of the study.

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

It is important that you tell your study doctor, Drs. Peter Carroll, MD, MPH, Matthew Cooperberg, MD MPH, Anthony Luke, MD, and June Chan ScD., if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her [redacted].

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

What are my rights if I take part in this study?

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

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

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

Who can answer my questions about the study?

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctor(s) Dr. Peter Carroll or Dr. Matthew Cooperberg, Anthony Luke, MD, and June Chan ScD [redacted].

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

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

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

About Using Tissue or Blood for Research

You are going to have a biopsy to assess your cancer and you will also be asked to donate blood for this study. For the biopsy, the doctor will remove some body tissue to do some tests. The standard of care clinical results (e.g. grade, stage, tumor volume from the biopsy) of these tests will be given to you by your doctor and will be used to plan your care.

We would like to keep some of the tissue or blood that is left over for future research. If you agree, this tissue or blood will be kept and may be used in research to learn more about cancer and other diseases. Please read the information sheet called "How Is Tissue Used for Research" to learn more about tissue research.

Your tissue or blood may be helpful for research whether you do or do not have cancer. The research that may be done with your tissue or blood 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 tissue or blood will not be given to you or your doctor. These reports will not be put in your health record. The research will not have an effect on your care.

Things to Think About

The choice to let us keep the leftover tissue or blood 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 tissue or blood can be kept for other future research, you can change your mind at any time. Just contact us and let us know that you do not want us to use your tissue. Then any tissue or blood 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 UCSF may give them reports about your health, it will not give them your name, address, phone number, or any other information that will let the researchers know who you are.

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

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

Benefits

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

Risks

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

Making Your Choice

Please read 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 research review board at 415-476-1814 Office of the Committee on Human Research (IRB's phone number).

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

1. My tissue or blood may be kept for use in research to learn about, prevent, or treat cancer.

YES	NO

2. My tissue or blood may be kept for use in research to learn about, prevent or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease).

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