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CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Informed Consent Form

Prostate 8 Study - II: A Randomized Controlled Trial of Diet & Exercise Interventions among Men with Prostate Cancer - II

This is a clinical trial, a type of research study. Your study investigators: Stacey Kenfield, ScD; Matthew Cooperberg, MD, MPH; Peter Carroll, MD, MPH; and Associates from the UCSF Departments of Urology, Orthopaedic Surgery, and Epidemiology & Biostatistics will explain the clinical trial to you. We are also collaborating with Jason Wiese, PhD, at the University of Utah.

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 urologist or study investigators.

You are being asked to take part in this study because you were diagnosed with prostate cancer and chose radical prostatectomy (RP) as treatment.

Why is this study being done?

Researchers at University of California at San Francisco (UCSF) have developed diet and exercise programs specifically geared toward men with prostate cancer. The research team is now looking for men to participate in a study called Prostate 8-II. The purpose of this study is to determine whether a 2-year wellness program focused on diet and exercise improves biological, clinical, and quality of life outcomes in men choosing surgery as primary treatment for prostate cancer.

The investigators do not have any financial or proprietary interests in this study. The National Institutes of Health is providing support for the conduct of this study.

This study will not prevent you from receiving the best care for the treatment of your cancer. The study will be in addition to whatever therapy is felt to be best for you throughout the length of the study.

How many people will take part in this study?

About 200 men will enroll in this study.

What are the study groups?

If you participate in this study you will be randomly assigned to one of four study groups named Group A, B, C, and D that each will receive different combinations of educational and supportive tools related to diet and exercise. You will be given your study schedule based on the group you are randomized to. Our exercise recommendations follow the principles of the American College of Sports Medicine physical activity guidelines for older adults and men with prostate cancer; and our diet recommendations are based on the peer-reviewed scientific literature on diet practices that have been associated with reduced risk of prostate cancer progression, the majority of which are consistent with recommendations for overall health.

Around the date of surgery, all groups will receive:

- Print educational materials about the benefits of exercise and diet for men with prostate cancer, provided in person or mailed around the date of surgery
- 10-week text messaging program focused on your recovery after RP surgery, starting about 2 weeks before surgery

By the end of the 2-year study, all groups will receive:

- A personalized exercise and/or diet report based on your survey responses
- Heart rate monitor to wear during exercise
- Resistance bands to use during exercise

Depending on your group assignment, you may also receive:

- Access to an online portal with additional educational materials to help improve diet and exercise habits and various tools, such as the ability to track your diet and exercise
- Additional educational print materials on diet and exercise
- Additional text messages over 2 years that supports healthy exercise and diet habits
- One 45-60-minute phone session at the start of the study followed by eight 30-minute quarterly phone sessions with an exercise coach over 2 years. These sessions will be recorded (with your permission).
- One 45-60-minute phone session at the start of the study followed by eight 30-minute quarterly phone sessions with a diet coach over 2 years. These sessions will be recorded (with your permission).

Regardless of the recommendations and educational advice you receive, there is no restriction on your daily exercise/diet while you are in the study. We want to learn if the program will change your lifestyle.

How long will I be in the study?

You will be asked to actively participate in the study for approximately 2 years. Following the completion of the study, we will follow your treatment and disease status on a yearly basis for 3 more years. We would like to do this by contacting you by phone, email, or mail once a year, having you complete a short questionnaire and reviewing your medical records. Keeping in touch with you and checking on your condition helps us look at the long-term effects of the study.

In summary, your time commitment for participating will be:
Baseline: 3 hours 30 min
Prior to surgery: 45 min
6 months after surgery: 3 hours
12 months after surgery: 3 hours
24 months after surgery: 3 hours
+ 5 hours dietary counseling (over 2 years) if randomized to a group provided dietary counseling
+ 5 hours exercise counseling (over 2 years) if randomized to a group provided exercise counseling
+ up to 1 hour call in a subset of participants to assess study acceptability, with your permission

What are the first steps if I agree to take part in this research study?

If you are interested in participating, the following steps will be taken to determine if you are eligible to enroll:

- Full eligibility will be assessed in a survey. You will be asked questions regarding your current exercise habits and health conditions (heart, metabolic or kidney disease or signs and symptoms) that may affect your ability to exercise safely.
- You may need additional clearance from your doctor to participate in physical activity if you have certain health conditions or symptoms (see above).
- You will be asked whether you have regular access to the Internet (via a computer, tablet, or phone) and text messaging capabilities on your phone.

If you consent to participate in the study, the following procedures will occur:

- Complete a set of online questionnaires on your demographics, medical history, lifestyle habits, and quality of life.
- Complete 24-hour online diet recalls. It takes 20-30 minutes to complete the diet recall each day. Two recalls are requested at baseline, and a total of 5 (3 additional) are requested during the 2-year study.
- Wear an accelerometer for 7 days (this is a small physical activity monitor worn around your wrist). The accelerometer and instructions may be mailed to you or given to you in the clinic, and you may be asked to mail it back in a pre-paid envelope or bring it in with you when you come to a clinic visit.
- Limited physical assessment (weight, height, hip & waist circumference, blood pressure).
- Review past medical history.
- On-site blood collection at UCSF, or alternatively, a local LabCorp, as needed.
- Provide a urine sample if attending UCSF for the study visit.

After completion of the baseline assessments, you will be randomized to one of four groups. Randomization means that you are put into a group by chance. A computer program will place you in one of the groups. Neither you, your doctor, nor the study investigators can choose the group you will be in. You have an equal chance of being placed in any one of the groups.

If you are randomized to a group that is offered exercise coaching, you will be asked to wear a heart rate monitor every time you perform any exercise. You will receive a handout with instructions to setup the chest strap heart rate monitor app on your smartphone; we will ask your permission to access these data collected in the app remotely throughout the study so that you and your coach can see your exercise data in the online portal. If you don't have a smartphone, you will receive a watch that will sync with the heart rate monitor.

What's expected of me during the study if I choose to participate?

Once you complete the baseline assessments, you will be randomized and have access to the study tools allocated to your group. You will be told at randomization what combination of education and tools you will receive and the schedule for receiving these tools.

Here is a list of the educational materials and tools that everyone will receive, but at different points during the study:

Print and/or web-based materials – Each group assignment will receive detailed educational materials on diet and exercise.

Heart rate monitor and resistance bands – If you are in a group that receives these tools at the beginning of the study, we ask that you use the heart rate monitor when you do any exercise, and use the resistance bands if instructed to do so by your exercise coach during the study. If you are in a group that does not receive these tools at the beginning of the study, they will be given to you when you complete the 24-month study assessments.

Personalized lifestyle report – A report will be provided to you at the beginning or at the end of the study, based on your survey responses.

10-week text messaging program beginning about 2 weeks before RP surgery – This program focuses on your recovery after RP surgery. About 5 texts are sent prior to surgery; most of the texts start the day after RP surgery. It includes about 35 texts over 10 weeks, or about 4 texts per week. Any charges from your service provider are your responsibility. The study is providing each participant a payment to offset any texting costs (detailed below).

Based on Random Group Assignment, some participants will also receive:

Coaching – If your group assignment includes an exercise coach (exercise trainer), you will have access to 9 telephone-based consultations over 2 years. If your group assignment includes a diet coach (registered dietitian), you will have access to 9 telephone-based consultations over 2 years. These calls will be scheduled in advance on a quarterly basis. The coach will provide a report to you after the phone call. Your coach will help you set your own diet and/or exercise goals but you will also be able to do this on your own during the study. The choice of what exercises you do or what dietary items you wish to focus on is up to you.

If randomized to a group that receives lifestyle coaching (diet and/or exercise), I give permission for the researchers to record my calls for research purposes/study reporting. My name or identifying information will not be used when reporting on this research.

YES	NO

Text messaging – If your group assignment includes a 2-year text messaging program, you will receive approximately 4 text messages per week focused on making healthy lifestyle choices. Some of the texts will ask you questions; please reply to these text messages. You will receive the 10-week text program focused on your recovery (see above). Then, you will continue to receive the program on making healthy lifestyle choices. Any charges from your service provider are your responsibility. The study is providing each participant a payment to offset any texting costs (detailed below).

Access to an online portal – If your group assignment includes access to the portal, you will have access to additional tools to help you meet your goals. For example, you will be able to track

specific habits once enrolled in the study. What you choose to track is up to you. You will be prompted to track for at least 2 weeks prior to a coach appointment, in order for your coach to provide you tailored feedback on your diet and/or exercise.

Other Study Procedures

Each group will complete the following assessments during the study, outlined in the table below:

Study Assessments for All Groups

Assessments	Pre-Baseline	Baseline	Before or at RP[1]	6 months after RP	12 months after RP	24 months after RP
Questionnaires (lifestyle habits, quality of life, sleep, barriers and self-efficacy, satisfaction with cancer care, study acceptability)	X		X – subset of questions	X	X	X
Diet recall[2]	X			X	X	X
Accelerometer worn for 7 days	X			X	X	X
Height, weight, waist and hip circumference, blood pressure[3]		X	X	X	X	X
Blood draw[3]		X	X	X	X	X
Urine sample[4]		X		X		
New illnesses, injuries, hospitalizations, quality of life		Short survey sent before RP, and 4 and 12 weeks after RP, then quarterly				
Phone call to access study acceptability[5]			X - In a subset of participants			
Tissue collection	Request archival samples from biopsy & RP					

[1] "Before or at RP" assessments are optional for men enrolled <4 weeks prior to surgery due to the short time from baseline to pre-RP time point.

[2] Two 24-hour recalls are requested at baseline, and one 24-hour recall at 6, 12 and 24 months.

[3] Body size and blood assessments will be done at UCSF or a local LabCorp of participant's choice at baseline, before or at RP, and 6, 12, and 24 months after RP.

[4] Urine samples are collected only at UCSF study visits. If a sample was not collected at baseline but the patient plans to visit UCSF 6-months post-surgery, a urine sample may be collected on the day or close in time to surgery (Before or at RP).

[5] The study team will conduct interviews through Zoom or similar application with a subset of participants. The calls will be recorded with participants' permission. Both you and the researchers will be provided with a unique ID, teleconference phone number, and access code for the call. A representative from the University of Utah or UCSF investigator will conduct this interview. A UCSF investigator or research coordinator will manage the call. You will be identified to Univ. of Utah researchers using a unique study identifier; your name and medical record number will not be shared by UCSF. The interview will last 45-60 minutes. The audio-recording will be kept until the research study is completed.

Additional information on the assessments for both groups are outlined below

To understand more about how prostate cancer responds to diet and exercise, your research blood and urine samples and tissue from your biopsy and RP may be used to look for proteins or genes that may be linked to lifestyle factors and/or cancer progression, as well as changes in biomarker expression over time. We may examine markers of metabolism, immune response, inflammation, or oxidative stress, as well as other hypotheses in the future.

Locations for Study Visits

Study procedures will be done at the UCSF Urology Outpatient Clinic at Mission Bay Precision Cancer Medicine Building. However, if you do not live within driving distance of UCSF or prefer to complete the assessments locally, we may be able to offer these visits at a local lab, and we will inform you of the change. Your visit 12 months after surgery can be completed at a local lab (for example LabCorp/Quest) and we will inform you of those details before this time point. During these visits, they will draw your blood and measure your height, weight, waist circumference, blood pressure, and pulse. Blood will be collected after a minimum of 12-hour water-only fast. You may take your normal daily medications. It takes approximately 15-20 minutes to complete the blood draw and body measurements.

Blood drawing (venipuncture): Blood will be drawn by inserting a needle into a vein in your arm. Each blood sample taken at UCSF at baseline, before RP, and 6 months will be approximately 100-120 cc (20-24 teaspoons); each blood sample taken at LabCorp at 12 and 24 months will be approximately 40 cc (8 teaspoons). A total of about 88 teaspoons (440 cc) will be drawn for the whole study. You will be asked not to eat or drink anything but water for 12 hours and not to exercise vigorously for at least 48 hours prior to the blood draw. You may take your normal daily medications. We ask that you drink plenty of water prior to your blood draw, and that you bring a snack/food item of your choice with you to eat after the blood draw. If you have your blood drawn at UCSF, we will have snacks on hand in case you forget. Metabolic markers, such as a lipid panel, C-reactive protein (CRP), fasting glucose, and HbA1c will be assessed at the time of blood draw and these assessments may be added to your medical record.

Urine sample: If you are coming to UCSF, we will ask you to collect the first urine you pass of the day at baseline or pre-RP and 6 months. You will be provided with a container and asked to record the time of collection. You will bring this container with you to your visit.

Tissue collection: We ask for your permission to access available archival tumor blocks or tumor slides from your biopsy and surgery (RP). This is being done so that researchers can examine tissue-based markers of metabolism, immune response, inflammation, or oxidative stress as well as other pathways identified in the future that may play a role in the association between lifestyle factors and cancer recurrence/progression.

Questionnaires: You will be asked to complete a set of online questionnaires at home 5 times over the 2-year period. Completion of the questionnaires will take approximately 60-90 minutes at home. You do not have to complete the surveys in one sitting – you can save and return to the surveys at a later time; we ask that you complete each survey set within 1 week. The surveys include questions on your demographics and health history, exercise habits, diet, smoking history, and physical and emotional health (including psychological distress, fatigue, pain, sleep quality,

memory, motivation, general and prostate-specific quality of life), satisfaction with cancer care, and acceptability of the study materials. Completion of the diet survey (administered 4 times over the 2-year period) may take 30-45 minutes; this is the longest survey in the set. If any questions make you feel uncomfortable, you may skip those questions and not give an answer. If assigned to a group with coaching, your coach may view your answers pertaining to your diet and exercise preferences and habits (asked on the baseline survey), in order to provide personal diet and exercise recommendations to you.

Periodically during the study (every 2-3 months), you will also be asked to complete a short questionnaire online to report any injuries, illnesses, or hospitalizations, and your sleep quality. If you do not do this short questionnaire online, a member of the research team may call you to ask you the questions over the phone. It takes about 5-10 minutes to complete this questionnaire.

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. 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?

Please review the following risks and side effects that are anticipated in this study. We will monitor all groups for safety and ask you about any changes in health, related or unrelated to the study, approximately every 2-3 months during and at the end of the 2-year study period. We encourage you to report any changes in your "health or side effects" during the study by calling the study coordinator [redacted] or emailing [redacted]. We will notify the study doctors, including Dr. Cooperberg or Dr. Carroll, to any health changes or side effects.

PHYSICAL RISKS

As part of this study you may increase your physical activity level. Normal body responses that you may experience *during* exercise include increased heart rate, increased breathing rate, mild muscle discomfort, and mild fatigue. Normal body responses that you may experience *following* exercise include muscle soreness or discomfort and general and/or specific fatigue. In order to minimize these risks, you will be asked to read guidance on safe exercise and how to perform a warm-up and cool-down before and after each exercise session. Tiredness and soreness usually go away after two to three days. With any form of regular exercise, the risk of injury is slightly increased. There is the possibility of muscle pulls or strains. During exercise, it is possible to experience moderate shortness of breath, wheezing or leg cramps; if any of these conditions worsen and you feel you cannot continue exercising, STOP, and talk to your doctor. During your workout, if you experience any of the following, please STOP EXERCISING and CALL 911: onset of moderate-to-severe chest pain or numbness in the left arm, severe or unusual shortness of breath, extreme fatigue, skeletal fracture, failure of muscle coordination, vertigo (illusion of dizzying movement), visual problems (e.g., tunnel vision, blurred vision), gait pattern problems, or confusion.

You can ask the study team questions about side effects at any time. [redacted]

Rare risks for all patients

Blood Collection – There are minor risks associated with blood draw (i.e., bruising, infection, discomfort, light-headedness). However, this procedure will be performed by a trained phlebotomist. No syringes, lancets, needles or other devices capable of transmitting infection from one person to another shall be reused. All of these items will be destroyed after each use.

Other exercise risks – Exercise may cause temporary risks of an adverse cardiovascular event, such as a heart attack. The screening procedures for this study, including our screening questions, medical record review, and doctor's clearance if you have certain medical conditions, are designed to tell us whether you are healthy enough for exercise. Only men who are determined to be healthy enough will be eligible to continue with the study. Nevertheless, there is a small risk of an adverse cardiovascular event.

Randomization risks – You will be randomly assigned to one of four groups. The educational and supportive tools you receive may not be effective in helping you cope with your disease or the treatment side effects. This means you may spend time in the study and experience side effects that may not provide you with any health-related benefits.

Unknown Risks – The educational and supportive tools you receive 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, please ask the study investigators by calling [redacted] or emailing [redacted].

Are there benefits to taking part in this study?

You may or may not personally benefit from being in this study. However, by serving as a participant, you may help us learn how to benefit patients in the future.

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

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and can still get your care from our institution the way you usually do.

You can participate in other research studies at the University of California, San Francisco (UCSF) (if available and you are eligible) or you can choose not to participate in any research studies. You can also seek dietary and exercise advice and guidelines outside of the study. 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. The conduct of this research involves the collection, access, and use of identified personal information. 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 your Standard of Care hematology and blood chemistry tests will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation in this study and of any information added to your medical record as a result of your participation. You may have the Decipher Score test done as part of your clinical care. We request access to your test result for research. Study tests that are performed by research labs, and information gathered directly from you by the researchers (for example, the questionnaires that you complete), will be part of your research records but will not be added to your medical record. Data from your medical record will be stored securely in the Urology Outcomes Database (an electronic database which support clinical care, CHR #11-05329) and may be used for clinical research, and in our secure study database. 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 personal information will only be shared with other parties if required by law. No personal identifying information will be included in publications or presentations that results from this research.

Your data collected during the study will be de-identified using a unique identification (ID) number assigned to you for the study, not with your name. Only the site investigator, exercise physiologist, research coordinator and other personnel working directly on the study will have access to information that links your name with your ID number.

Donating specimens may involve a loss of privacy, but information about you will be handled as confidentially as possible. The manager of the Genitourinary Tissue Bank and select tissue bank staff members will have access to information about you but they will not release any identifying information about you to researchers using your specimens.

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

- University of California, San Francisco
- The National Cancer Institute (NCI)

What are the costs of taking part in this study?

You will not need to pay to be a part of this research study. However, any text messaging charges incurred are the patients' responsibility.

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?

All participants will receive up to $150 to offset parking and texting costs. This will be in the form of gift cards using a pro-rated system wherein participants will receive up to a $50 gift card for the completion of the 6-month, 12-month and 24-month study-related assessments ($25 for surveys, $25 for biospecimens) at each timepoint.

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

It is important that you tell your study investigator, Stacey Kenfield ScD at [redacted], if you feel that you have been injured because of taking part in this study. You can also tell Dr. Cooperberg or Dr. Carroll in person or call the study investigators [redacted] or email [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 of California 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 are free to withdraw your consent and discontinue your involvement 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.

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?

We are happy to answer any questions you may have about the study and talk to you about any concerns or complaints you have. Please do not hesitate to contact your study investigators, Stacey Kenfield ScD, Matthew Cooperberg, MD, MPH; and Peter Carroll, MD, MPH [redacted] or [redacted].

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

A description of this clinical trial is available at http://www.ClinicalTrials.gov (NCT#03999151), as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of your results. You can search this website at any time. If you want

more information about this study, ask your investigator.

What will happen if I agree to donate my specimens?

Donation of Specimens for Research

You are asked to donate blood and urine for this study. Additionally, with your permission, we would like to request access to available archival tumor blocks or tumor slides from your biopsy and surgery (radical prostatectomy). This is being done so that researchers can examine biological markers of prostate cancer to improve treatment of this disease and tissue-based markers of metabolism, immune response, inflammation, or oxidative stress, and how these markers change over time while you are in the study. If you have received biopsies and/or surgery from UCSF or other institutions, we will contact these facilities to ask if we can obtain material from your initial biopsy and radical prostatectomy if it is not being used for your care.

I give permission for the researchers to request my archived tumor blocks and tumor slides from my biopsy and radical prostatectomy to learn about, prevent, or treat cancer.

YES	NO

Optional Donation of Specimens for Future Research

If you agree to let researchers collect and store your specimens for future research, the following will happen:

- Your blood and urine samples will be stored at the Genitourinary Tissue Bank located at the UCSF Helen Diller Family Comprehensive Cancer Center.
- After all routine tests required for your care are finished, instead of discarding your leftover specimens we will save them in what is called a “tissue bank/biorepository” for possible future research. We also will collect and save information from your medical record, including clinical history including laboratory and pathology reports related to your prostate cancer, diagnostic tests, medical questionnaires and histories, diagnoses, treatments, etc. We do not know for sure if your specimens or medical record will be used, but they might be used in research about cancer or other diseases. Genetic information taken from the specimens (also known as genotype data) and the medical record data (also known as phenotype data) may be shared broadly in coded anonymous form.
- We may give your specimens and certain medical information about you (for example, diagnosis, age) to other scientists or companies not at UCSF, including to a government

health research database, but we will not give them your name, address, phone number, or any other information that would identify you. Reports about any research 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.

- Sometimes specimens are used for genetic research (about diseases that are passed on in families). Even if we use the specimen for genetic research, we will not put the results in your medical record. The research will not change the care you receive. Your specimen and any information about you will be kept until it is used up or destroyed. It may be used to develop new drugs, tests, treatments or products. In some instances these may have potential commercial value. Your personal health information cannot be used for additional research without additional approval from either you or a review committee.

- Your specimens will be kept indefinitely. If you decide later that you do not want your specimens and information to be used for future research, you can notify the investigator in writing at Dr. Stacey Kenfield, Department of Urology, [redacted], San Francisco, CA, 94143, and we will destroy any remaining identifiable specimens and information 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.

What risks are involved with donating specimens for research?

Confidentiality: Donating 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. The manager of tissue bank and select tissue bank staff members will have access to information about you but they 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.

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. These facts are important because they will help us learn if the factors that cause cancer to occur or get worse are the same or different based on these facts. Thus it is possible that study finding could one day help people of the same race, ethnicity, or sex as you. However, it is also possible through these kinds of studies that genetic traits might come to be associated with your group. In some cases, this could reinforce harmful stereotypes.

What are the benefits of donating specimens for research?

There will be no direct benefit to you from allowing your specimens 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.

What financial issues should I consider before donating?

You will not be charged for donating your specimens. You will not be paid for donating your specimens. 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. UCSF may receive payment from researchers requesting specimens in order to cover the costs of collecting and storing the specimens.

What alternatives do I have?

If you choose not to donate your specimens for future research, any leftover blood, urine and/or tissue not needed for diagnosis will be thrown away.

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.

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. **You can say "yes" or "no" to each of the following studies.** If you have any questions, please talk to your doctor or nurse, or call our research review board, the Committee on Human Research at 415-476-1814. No matter what you decide to do, it will not affect your care.

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

YES	NO

2. My blood and urine 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 the 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

Please specify a phone number that can receive text messages:

Phone number: _____

Please specify an address that can receive packages/large envelopes for study assessment/material mailings:

Address: _____

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