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

CC#: 135513 A Multidisciplinary Team-Based Approach to Mitigate the Impact of Androgen Deprivation Therapy in Prostate Cancer: a Randomized Phase 2 Study.

The "STAND" (Supportive Therapy in Androgen Deprivation) Clinic

This is a clinical trial, a type of research study. Your study doctor, Rahul Aggarwal M.D., and his associates from the University of California, San Francisco (UCSF), Division of Hematology/Oncology, Department of Medicine, 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 prostate cancer and are a candidate for, or have started, androgen deprivation therapy (ADT; ie. hormone therapy) for your cancer.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to determine how to best improve health outcomes and manage the potential side effects of hormone therapy. Side effects of hormone therapy include hot flashes, fatigue, decreased interest in sex, loss of bone density, weight gain, and mood changes, among others. Our current approach to address these issues is to evaluate patients in clinic every 3 months, perform counseling and education during the course of the visit, and if necessary, refer patients to exercise, nutrition, and/or symptom management services.

The STAND clinic was created to offer a structured approach for men receiving hormone therapy. Clinic participation consists of monthly visits with Nutrition, Exercise, and Symptom Management services on a rotating basis, as well as self-directed patient education sessions.

It is not known whether participation in a structured program such as the STAND clinic, versus the current approach outlined above, leads to better outcomes with respect to potential side effects of hormone therapy. This study is being done to compare these two approaches and help decide which is better in improving the following factors: changes in your percentage body fat and factors that affect your metabolism, your bone health, and your quality of life.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Up to 100 people may participate in the study at UCSF.

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

Participants in this study who are not receiving current chemotherapy will be randomized into 1 of 2 groups. Randomization means that you are put into a group by chance (like rolling dice). 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 (one in two) chance of being placed in any group.

If you are placed in group 1 (standard of care treatment), you will have clinic visits every 3 months and receive current standard of care therapy outlined above. During the visits there will be:

- A review of your medical history and current medications
- Assessment of the impact of hormone therapy on body composition and certain laboratory tests (e.g. fasting cholesterol levels)
- Toxicity assessment
- Lifestyle modification counseling and review of quality of life and side effects of androgen deprivation therapy (ADT; ie. hormone therapy) with questionnaires by a trained nurse practitioner and/or physician. Quality of life questionnaires cover various items including your mood, energy level, severity of hot flashes, and overall functional level. The questionnaires will take approximately 20-30 minutes to complete, and can be completed electronically prior to your visit or on paper during the course of your visit. The PHQ-9 questionnaire screening for depression will be completed in person during your study visit.
- Medication management including hormone injections
- Referrals to exercise, nutrition and symptom management services upon patient request or if deemed necessary by your health care provider. You will have the option of visiting with each of these services as many times as necessary during the course of the study.

After 12 months on study, patients in group 1 will have the opportunity to participate in the STAND clinic for the next 12 months or for the duration of their hormone therapy treatment.

If you are placed in group 2 (STAND clinic), in addition to visits with your health care provider every 3 months and assessments as outlined above, you will participate in the STAND clinic. The STAND clinic consists of monthly clinic visits in which you will see the following services on a rotating basis:

- Nutrition counseling
- Exercise training
- Symptom management by trained physician and/or nurse practitioner

In addition, every month you will view an education "module" during your visit, consisting of Powerpoint slide presentations covering the various aspects of hormone therapy.

All patients currently receiving or planning to receive chemotherapy will be placed into Group 2 (STAND clinic).

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 can be in the main part of 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. You will also have some procedures that are only being done because you are in the study. These are listed as research procedures. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

You must complete the following procedures within 6 weeks prior to day 1 of the study. Your visit may take about 1-2 hours.

- Physical exam
- Review of medical history and assessment of other medical conditions
- Weight, body mass index.
- Blood draw (about 2 tablespoons) for PSA, if not already receiving ADT.

Research Procedures:

- Review of medications that you are taking
- DXA Bone Density Scan: An imaging test that measures bone density (the amount of bone mineral contained in a certain volume of bone) by passing x-rays with two different energy levels through is used to diagnose osteoporosis (decrease in bone mass and density). A bone density scan, using a central machine, takes about 15 minutes, including registration. During the procedure, you will lie on a table scanner for five to eight minutes.
- Measurement of exercise patterns: Your physical activity will be measured using an accelerometer. This is a small plastic device (about 2 inches on each side) that is worn on an elastic waistband around your waist for 7 consecutive days. It must be kept on at all times except when bathing or swimming (it is *not* waterproof).
- Measurement of the ratio of the length of your 2nd and 4th digit of your right hand
- Optional CT scan of the radius and tibia (long bones of the arm and leg)

During the main part of the study...

If the exams, tests and procedures show that you can be in the main part of the study,

and you choose to take part, then you will randomized with equal probability to one of the two study "arms" or groups (current standard of care or participation in the STAND clinic).

Regardless of your assignment, you will also be placed into one of four strata (subgroups), taking into account the duration of hormone therapy prior to study entry and body mass index at study entry.

All patients will have the following visits

Day 1 (the visit will take about 1 hour)

- Physical exam
- Height, weight, body mass index, and percent body fat measurement
- LHRH Analogue (hormone injection). If you have already started hormone therapy, you will be kept on the same schedule as before and may not receive hormone injection on the day 1 study visit. Hormone therapy can include Eligard, Zolodex, Trelstar, or Leuprolide Acetate; you and your doctor will discuss which brand you receive. There are no significant differences in treatment effect nor side effects between brands.
- Blood (about 1-2 tablespoons) will be drawn for
    - Fasting lipid/glucose panel and insulin level
    - Hemoglobin A1c (to measure glucose levels)
    - Serum 25-(OH) vitamin D level
    - Serum PSA –a protein produced by the prostate gland, that is used to monitor treatment response
    - Serum testosterone

You will need to fast for at least 10 hours prior to the blood draw.

Research Procedures:

- Review of medications that you are taking
- Questions about how your disease is affecting your daily life
- Quality of life questionnaires
- Questions about your nutritional habits.
- Blood (about 1 tablespoon) will be drawn for:
    - Studying metabolism changes of your cells which may help researchers understand how drug therapies and interventions may be working.
    - Banking - the researchers would like to collect and store (bank) your blood for future research. To protect your privacy, your blood samples will be identified by your subject number, not your name. These samples will be stored at UCSF indefinitely. The researchers and authorized members of this research study will have access to the samples and data collected. The samples will be destroyed when they are no longer needed.

- Your blood will be used only for research and will not be sold. The research done with your specimens may help to develop new products in the future. You will not be paid for donating blood. If any discoveries or commercial products are made as a result of research done on your blood, neither you nor your family will receive any financial benefits or compensation.
  In the future, we may give your specimens and certain medical information about you (for example, diagnosis, blood pressure, age if less than 85) to other scientists or companies not at UCSF, including to 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.
- 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 personal health information cannot be used for additional research without additional approval from either you or a review committee.

  - Optional blood collection to examine genetic changes. Please refer to "Using Blood for Research" section at end of form.

The following will be done at the end of every 3 months (the visit will take about 1 hour):

- Physical exam
- Weight, body mass index, and percent body fat measurement
- LHRH analogue (hormone injection)
- Referral to Nutrition, Exercise, and Symptom Management Services upon your request or if deemed necessary by your health care provider
- Counseling with health care provider to discuss lifestyle modifications, review laboratory results
- Blood (about 1-2 tablespoons) will be drawn for
  - Fasting lipid/glucose panel and insulin level
  - Hemoglobin A1c (to measure glucose levels)
  - Serum 25-(OH) vitamin D level
  - Serum PSA

You will need to fast for at least 10 hours prior to the blood draw.

Research Procedures:

- Review of medications that you are taking
- Questions about how your disease is affecting your daily life
- Quality of life questionnaires
- Measurement of exercise patterns (accelerometer) during month 6
- Blood (about 1 tablespoon) will be drawn for:
    - To study metabolism changes of your cells
    - Banking

Patients in Group 2 (STAND clinic), will have the following additional, monthly visits.

During the course of these monthly visits, there will be a series of self-guided educational modules discussing various aspects of ADT and management of side effects. These modules will be a series of PowerPoint slides that you view during your visit. You will have the opportunity to ask questions before and after you view each module. These will also be available to all patients for review outside of the clinic.

You will have individualized sessions with exercise physiologist, registered dietitian, and symptom management services. You will see one of these providers each month on a rotating basis for the 12 month duration of the clinic. In total, you will visit with each service four times during the course of the year. The STAND clinic visits will take about 1-2 hours.

All patients will have the following end of the study visit (12 months):

You will have an end of treatment visit at approximately 12 months after beginning the study. The visit will take about 2 hours and the following tests and procedures will occur:

- Physical exam
- Weight, body mass index, and percent body fat measurement
- Counseling with health care provider to discuss lifestyle modifications, review laboratory results
- Blood (about 1-2 tablespoons) will be drawn for
    - Fasting lipid panel/glucose and insulin level
    - Hemoglobin A1c (to measure glucose levels)
    - Serum 25-(OH) vitamin D levels
    - Serum PSA
    - Serum testosterone

You will need to fast for at least 10 hours prior to the blood draw.

Research Procedures:

- Review of medications that you are taking
- Questions about how your disease is affecting your daily life
- Quality of life questionnaires

- Questions about your nutritional habits
- Measurement of exercise patterns (accelerometer)
- DXA Bone Density Scan
- Optional CT scan of the radius and tibia (long bones of the arm and leg)
- Blood (about 1 tablespoon) will be drawn for
    - To study metabolism changes of your cells
    - Blood collection for banking

Follow Up Visits

If you are randomized to the group 1 (current standard-of-care study arm), you will have the option to participate in the STAND clinic after the end of study visit at 12 months. Patients who opt to participate in the STAND clinic will be followed for an additional 12 months. The STAND clinic schedule will be identical to that followed by patients initially randomized to the STAND clinic.

All patients who have completed the STAND clinic will be followed by telephone calls after 2 and 4 months to see how you are doing. At 6 months following completion of the STAND clinic, you will return for a clinic visit (the visit will take about 1 hour) and have the following procedures:

- Physical exam
- Weight, body mass index, and percent body fat measurement
- Counseling with health care provider to discuss lifestyle modifications, review laboratory results
- Blood (about 1-2 tablespoons) for:
    - Fasting lipid panel/glucose and insulin level
    - Hemoglobin A1c
    - Serum PSA
    - Serum testosterone

You will need to fast for at least 10 hours prior to the blood draw.

<u>Research Procedures:</u>

- Quality of life questionnaires
- Blood (about 1 tablespoon) will be drawn for
    - To study metabolism changes of your cells
    - Banking

STUDY LOCATION:

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

HOW LONG WILL I BE IN THE STUDY?

Participants in the group 1 will receive standard of care treatment for 12 months and may choose to participate in the STAND clinic for up to 12 months. Participants in group 2 will participate in the STAND clinic for 12 months. Participants in the STAND clinic will be followed for an additional 6 months after completion of the STAND clinic.

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, and they will tell you how to stop safely.

It is important to tell the study doctor if you are thinking about stopping, so that your doctor can talk about what follow-up care and testing could be most helpful for your cancer treatment.

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

WHAT SIDE EFFECTS OR RISKS CAN I EXPECT FROM BEING IN THE STUDY?

Risks and Side Effects Related LHRH analogs (Eligard, Zoladex, Lupron Depot or Trelstar):

Likely

- Hot flashes
- Fatigue
- Mild breast enlargement and pain
- Nipple tenderness
- Decreased interest in sexual activity
- Difficulty maintaining an erection
- Decreased bone mineral density

Less Likely

- Mood changes including depression
- Nausea and vomiting
- Swelling of your hands, feet and legs
- Low blood counts, which may cause fatigue, shortness of breath when walking, feeling more cold than usual
- Injection site burning and/or stinging

- Increased blood sugar levels
- Increased cholesterol levels
- Headaches

Rare but serious

- Increased risk of diabetes
- Increased risk of heart attacks or stroke

Risks related to Study Procedures

Randomization Risks: You will be assigned to a study arm by chance, and the treatment you receive may prove to be less effective than the other study.

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

Bioelectrical Bioimpedance Device for Assessment of Body Fat risks: The weak electrical current used to your body fat is not felt while using the monitor. Do not use, or allow others to use, this monitor if fitted with a cardiac pacemaker or other medical device. Pregnant women should not use this device

Quality of Life (QOL) Questionnaires risks: Answering the Quality of Life questionnaire may be an inconvenience. Some of the questions may remind you of unpleasant aspects of your therapy or disease, and you may experience some discomfort, anxiety or distress in answering such questions. You are free to decline to answer any questions you do not wish to answer, or to stop participating at any time.

Bone Mineral Density Scan (DXA) risks: The scanner uses beams of low energy radiation to determine the density of the bone or for soft tissue analysis.

Radiation risks: This research study involves exposure to radiation from two DXA Scans and two optional CT scans of the radius/tibia. 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 have any questions regarding the use of radiation or the risks involved, please consult the physician conducting the study.

Unknown risks: It is possible that unexpected side effects could occur or that the side effects could be more severe than anticipated. At this time, all the side effects of these

treatments are not known. Patients must report any unusual symptoms to their doctor immediately.

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 that participation in the STAND clinic or seeing nutrition, exercise, and symptom management services on a referral basis will mitigate the side effects associated with ADT treatment, there is no proof of this. We do know that the information from this study will help doctors learn more about the management of side effects of ADT treatment. This information could help future cancer patients.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

Your other choices may include:

- Getting treatment or care for your cancer without being in a study (i.e. hormone therapy).
- Taking part in another study
- Getting comfort care, also called palliative care - this type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer; comfort care does not treat the cancer directly, it works to improve how you feel and keep you as active and comfortable as possible
- 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?

We will do our best to make sure that the personal information in your medical record is kept private. However, we cannot guarantee total privacy. 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 National Cancer Institute (NCI) and other government agencies, e.g., the

Food and Drug Administration (FDA), involved in overseeing research

- The University of California

Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. A medical record will be created because of your participation in this study. Your consent form and some of your research test results will be included in this record. Therefore, your other doctors may become aware of your participation. Hospital regulations require that all health care providers treat information in medical records confidentially.

WHAT ARE THE COSTS OF TAKING PART IN THE STUDY?

You and/or your health plan/insurance company will need to pay for some or all of the costs of treating 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. Your study doctors or their clinical staff will obtain authorization from your insurance company prior to beginning your treatment. Taking part in this study may or may not cost you or your insurance company more than the cost of getting regular cancer treatment.

You will not be billed for any of the tests required specifically by the study. These are procedures noted above as “research procedures” in this consent form, such as DXA bone scans, blood drawn for research, and quality of life questionnaires. Other procedures, which are also done in this study but are part of your normal care, will be paid for by your or your insurance, such as hormone injections (these will be billed to you or your insurance as the Anddrogen deprivation therapy is standard of care for prostate cancer). This includes procedures that are considered part of the standard treatment for your cancer.

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 your study doctors, Dr. Aggarwal, MD, and his associates, if

you feel that you have been injured because of taking part in this study. You can tell him in person or call him [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, Dr. Aggarwal, MD [redacted].

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Office of the 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.

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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.

Using Blood for Research:

If you allow it, during the main part of the study, the study doctor would like to collect blood (about 1 tablespoon) to look for genetic changes (genotyping). The doctors would like to analyze your blood so that they can determine if there are inherited differences in a subset of your genes involved in hormone biology, which may affect treatment side effects. This information may help doctors to better manage the treatment side effects of future cancer patients.

The research is not designed specifically to help you. It might help people who have cancer and other diseases in the future.

Results from the analysis will be published but your data will not be reported individually. Reports about research done with your 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 allow the additional blood collection is up to you. No matter what you decide to do, it will not affect your care.

If you decide now that your blood can be drawn for genotyping, you can change your mind at any time. Just contact the study doctor, Rahul Aggarwal, MD [redacted], and let us know that you do not want us to use your blood. Then any blood that remains will no longer be used for research.

[redacted]

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.

Your blood will used for genetic research (about diseases that are passed on in families) during the study. Even when your blood is used for this kind of research, the results will not be put in your health records.

Your blood will be used only for research and will not be sold. The research done with your blood may help to develop new products in the future. You will not be paid for allowing your blood to be used in research even though the research done with your blood may help to develop new products in the future. You will not receive any payment or financial benefit from any products, tests, or discoveries derived from these samples.

Benefits

The benefits of research using 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.

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

1. I allow my blood to be collected for genotyping.

YES	*NO*

2. I agree to undergo the optional CT scans of the radius and tibia prior to start of the study, and also after 12 months.

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.

Participant	Date
Participant name (print)	
Person obtaining consent	Date
Person obtaining consent (print)	
Witness – Only required if the participant is a non-English speaker	Date