VA Department of Veterans Affairs VA RESEARCH CONSENT FORM

Subject Name: _____ **Date:** _____

Title of Study: Effect of Weight Loss on Prostate Cancer Pathology

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Co-Investigators: Zhaoping Li, M.D., Ph.D. Phone: (310) 268-3528

VAMC: VAGLAHS

INVITATION TO PARTICIPATE

You are being invited to take part in a research study at the VA Greater Los Angeles Healthcare System under the direction of Dr. William Aronson and his research team because you have prostate cancer, are scheduled for a prostatectomy, and considered to be overweight with a BMI (Body Mass Index) greater than 25. This study is designed to enroll 65 participants and we anticipate enrolling 65 from this medical center. Your participation in this study is expected to last about four to nine (4-9) weeks. Your participation in this study is entirely voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You should read the information below, and ask questions about anything you do not understand before deciding whether to participate.

1. PURPOSE OF THE STUDY

Obesity is a major public health concern, and may play an important role in the risk of developing prostate cancer and the growth of prostate cancer. The purpose of this study is to determine if losing weight has an effect on substances in your blood and prostate tissue that are related to prostate cancer growth. These substances are called growth factors. Prior animal studies suggest that losing weight can lower the amount of prostate cancer growth factors in the blood and prostate tissue. This information makes it important to us to find out more about any possible connection between weight-loss and the amount of growth factors in the blood stream and prostate tissue. In addition to doing studies on your blood and prostate tissue, we also will use a small amount of genetic material (the material inside each cell that is passed on from the parent to a child) from your prostate tissue to study the effects that losing weight may have on your prostate cancer.

This is a randomized study. This means that you will be assigned to one of two groups. You will have a 1 in 2 chance of being assigned to the control group (no weight-loss) or the weight-loss group. This assignment will be determined by chance. The process is similar to drawing cards or picking straws. This means your assignment to one of the groups is based on chance and not on a medical decision made by the study doctor.

2. PROCEDURES

We are only entering subjects into this research study that are overweight. As described below, you will have your study visits at the Veterans Administration. The total number of visits will depend on

whether you are placed in the weight-loss or no weight-loss group. If you volunteer to participate in this study, you will be asked to do the following things:

First Study Visit For Both Arms:

You will be asked to undergo the following procedures during the first study visit:

- Medical history and physical examination
- Measurement of your height and weight
- Measurement of your waist and hips with a measuring tape
- DEXA Scan: DEXA stands for Dual Energy X-Ray Absorptiometry. This is a test performed in the Nuclear Medicine Department at the VA that measures the amount of muscle, bone, and fat in your body through a computerized scanner. For this procedure, you will lie flat, face up, on an x-ray table for approximately 10 minutes as a very weak low intensity x-ray beam is passed across your body. This procedure is completely painless.
- Fasting Blood draw: About eight teaspoons of your blood (40ml) will be collected. You will be asked to fast for 10 hours prior to this blood collection. During the fasting period it is fine for you to drink plain water. We will measure the PSA, lipids, and various hormones and proteins in your blood.
- You will be given a Three-Day Food Diary form to complete over a 3-day period to determine the type and amount of food you eat.

This first study visit will take about 2 hours.

Study Phase

No Weight-loss Group: If you are assigned to the "no weight-loss group," you will not be given instructions on losing weight. Rather you will be asked to continue your usual dietary habits. You will be given/mailed two (2) Three-Day Food Diary forms to complete after your Baseline Visit and during the week prior to your scheduled prostatectomy to determine the type and amount of food you eat over a 3-day period of time. You will be given the option of mailing this form back to the research team, or bringing it to the VA hospital at a time that is convenient for you.

At your final visit prior to your prostatectomy, you will be asked to undergo the following procedures:

- Review of medications
- Review of adverse events (if you didn't feel well)
- Measurement of your weight
- Measurement of your waist and hips with a measuring tape
- Fasting Blood draw: About eight teaspoons of your blood (40ml) will be collected. You will be asked to fast for 10 hours prior to this blood collection. During the fasting period it is fine for you to drink plain water. We will measure the prostatic specific antigen (PSA), lipids, various

hormones and proteins in your blood. Your white blood cells will also be collected to study if weight loss affects inflammation.

- DEXA Scan

This study visit will take about 2 hours. You will then be counseled on the option of participating in a 5-8-week weight loss program after you have recovered from your prostatectomy. If you elect to undergo the optional weight loss program, you should contact the research coordinator, Sherry Jeffery, at 310-268-3670 to schedule your first appointment. The weight loss program will consist of 3 visits over 5-8 weeks. You will be instructed on daily meal plans that reduce the total number of calories you eat per day by 500 to 800 calories. You will also be instructed on daily exercise routines such as walking and stretching. These exercise routines will be personalized based on your capabilities and limitations. At each visit with the dietician you will be weighed, and you will be counseled on exercise routines and meal planning.

Weight-loss Group: If you are assigned to the weight-loss group, you will meet with a dietician weekly for four weeks and then every two weeks thereafter, up until the time of your prostate surgery. You will be instructed on daily meal plans that reduce the total number of calories you eat per day by 500 to 800 calories. You will also be instructed on daily exercise routines such as walking and stretching. These exercise routines will be personalized based on your capabilities and limitations. You will also be given a pedometer (device you wear on your belt or in your pocket that measures the number of steps you take) and an exercise log to record the amount of exercise you perform each day. At each visit with the dietician your exercise logs and the readings on your pedometer will be reviewed, you will be weighed, and you will be counseled on exercise routines and meal planning. At Baseline, Weeks 2, 4, and 8 your waist and hips will be measured with a measuring tape. You will be asked to complete a Three-Day Food Diary to determine the type and amount of food you eat over a 3-day period of time the week prior to each of your study visits and the week prior to your final visit. You will also have a DEXA Scan (to determine the amount of muscle, bone, and fat in your body) during the week prior to your final visit.

At your final visit prior to your prostatectomy, you will be asked to undergo the following procedures:

- Review of medications
- Review of adverse events (if you didn't feel well)
- Measurement of your weight
- Measurement of your waist and hips with a measuring tape
- Fasting Blood draw: About eight teaspoons of your blood (40ml) will be collected. You will be asked to fast for 10 hours prior to this blood collection. During the fasting period it is OK for you to drink plain water. We will measure the PSA, lipids, and various hormones and proteins in your blood. Your white blood cells will also be collected to study if weight loss affects inflammation.
- DEXA Scan

This study visit will take about 2 hours. You will be asked to continue your weight-loss regimen up until the time of your radical prostatectomy.

Date of Surgery: After your prostate is removed, the pathologist or pathology technician will examine the prostate tissue and make sure enough tissue is available to measure the amount and extent of your prostate cancer. The pathologist or pathology technician will then cut out four (4) small pieces (about one gram) of prostate tissue to be used for research by the study team. The investigators will study growth factors and genetic material in your prostate tissue that may affect prostate cancer growth. During your surgery a small sample (about a thimble full) of fat from around your prostate, from your incision and your inner abdominal wall will be collected to study if the weight loss affected inflammation in your fat.

Study Withdrawal: If you choose to withdraw from the study early, we would request that you allow us to take one more blood draw (eight teaspoons, 40ml) to measure your PSA, lipids, and various hormones and proteins in your blood. The study team will evaluate if there has been any change to the usual medications you take, and will evaluate if you are having any side effects. This visit will take about 45 minutes.

3. POTENTIAL RISKS AND DISCOMFORTS

If any of the doctors listed on this consent form is your treating physician, he (or she) is also an investigator for this study. As an investigator, he (or she) is interested not only in your clinical welfare, but also in the results of this study. It is possible that occasionally these two goals may be in conflict. At any time during this study, you may ask for a second opinion from another doctor who is in no way associated with this study.

You may experience the following risks and discomforts as a result of participating in this research study:

Weight Loss: Weight loss may result in a feeling of fatigue, loss of strength or a decrease in your ability to perform daily functions.

Exercise: Exercise may result in injury to your joints, bones and muscles. You may experience muscle soreness in your arms or legs, joint or bone pain, sprain your joints, or break your bones. You may also experience a heart attack.

Blood Drawing: When having blood drawn, you may experience some discomfort as a result of the needle prick in your arm. Some bruising or slight bleeding may occur. Although infection is possible, it is extremely rare, because the needle is sterile and disposable. Occasionally, people feel lightheaded or faint when blood is drawn.

3-Day Food Diary: The 3-Day Food Diary will require several hours to complete over a 3-day period. You may find this time commitment inconvenient.

Radiation exposure from DEXA Scan: We are exposed to radiation on a daily basis both from natural (sun and earth) and man-made sources. The average radiation dose from these sources for those living in the United States is 363 millirem per year. Exposure of up to 5,000 millirem of radiation is allowed and considered safe in individuals who use radiation in their work such as radiologists. Radiation exposure from a chest x-ray is about 125 millirem. By comparison, the radiation exposure from a DEXA scan is approximately 10 millirem. There is no known risk associated with the radiation exposure from receiving a DEXA scan.

Delay of Surgery: Delaying your surgery for 4-9-weeks may also cause you some anxiety. You have the option of not participating in this trial to avoid this anxiety.

As with any treatment, certain food products may cause an allergic reaction. If you have allergies to food products or medicines you should tell your study doctor.

If you experience any symptoms or medical problems during your participation in the research study, please contact the research team and let them know the problems you are experiencing. In addition to the risks listed above, the treatment or procedures in this study may involve risks that are currently unforeseeable.

4. ANTICIPATED BENEFITS TO SUBJECTS

No benefit can be promised to you from your participation in this study.

5. ANTICIPATED BENEFITS TO SOCIETY

The results of this study may lead to larger studies evaluating weight-loss for treating prostate cancer and new ways to treat or prevent prostate cancer.

6. ALTERNATIVES TO PARTICIPATION

You may choose not to participate in this study. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. If you choose not to participate, it will not have any effect on your medical care for your prostate cancer.

7. REIMBURSEMENT (PAYMENT) FOR PARTICIPATION

There will be no payment for participation in this study. You will be compensated for your travel

miles for research related visits. After each study visit the VA cashier will compensate you for miles you traveled at the standard VA rate. The present rate is 48.5 cents per mile. This rate may change in the future.

8. POSSIBLE COMMERCIAL PRODUCTS

This study will not result in the development of any commercial product.

9. FINANCIAL OBLIGATION

You will not be charged for any treatments or procedures that are part of this study. However, if you are required to make co-payments for services provided by VA or if you receive treatment that is part of your usual medical care, you or your third-party payer (e.g. insurance company) may be billed.

10. EMERGENCY CARE AND COMPENSATION FOR INJURY

In the event that you sustain an injury or illness as a result of your participation in this VA approved research study, all medical treatment (emergency as well as medical treatment beyond emergency care) will be provided by the VA. You will be treated for the injury at no cost to you. However, no plans or funds for additional compensation have been set aside. You have not waived any legal rights or released the hospital or its agents from liability for negligence by signing this form.

In the event of a research related injury or if you experience an adverse reaction, please immediately contact your study doctor at 310-268-3446 during the day and paged at 310-825-6301 after business hours. If you need emergency hospitalization in a private hospital because you are unable to come to the VA, have a family member or friend contact your study doctor so that the VA can coordinate care with the private hospital.

11. PRIVACY AND CONFIDENTIALITY

Participation in this study will involve a loss of privacy, but information about you will be handled as confidentially as possible. While the VA and the researchers on the team will do everything to prevent any loss of information, in the event that there is a breach of information, you will be contacted by the VA directly.

All records containing personal information, research data, and related records will be stored in locked files in Dr. Aronson's West LA VA research office, Building 500, Room 6613. All data that will be collected will be assigned with a personal identification code to protect personal privacy. It will be accessible only by members of the research team named above. After all the data has been

analyzed, it will be kept in storage for five years, after that it will be destroyed by a paper shredder. Your information will be combined with information from other people taking part in the study. We will keep confidential all research records that identify you to the extent allowed by law. However, you should know that there are some circumstances in which we may have to show your information to other people. For example, someone from the Food and Drug Administration, the Office of Human Research Protections, the Government Accounting Office, the VA Office of Research Oversight, our Institutional Review Board, our Data and Safety Monitoring Board and the Research Compliance Office may look at or copy portions of records that identify you, including your medical record; the sponsor may look at, but not copy, portions of the records that identify you, including your medical record. In addition, please note that VA policy requires that a note be written in your medical record concerning the consent process and your enrollment in this study. Thus non-research VA staff will have access to that information in the course of clinical care.

In addition, in accordance with California law, confidentiality cannot be guaranteed if the investigator becomes aware that you may be a danger to yourself or to others, or becomes aware that acts of child abuse or elder abuse may have occurred.

We may write about the combined information we have gathered, however, any presentations or publications from this information will not identify you.
At the end of this form you will be asked for your permission to allow the VA to share your Personal Health Information with the research team for use in this study. Your separate signature on that part of the consent form will reflect your official authorization.

12. PARTICIPATION AND WITHDRAWAL

Your participation in this research is voluntary. You have the right to leave the study at any time. If you choose to stop participating, that will not affect your relationship with the VA or the care that you may receive here.

12a. CONSEQUENCES OF WITHDRAWAL

There are no known consequences of withdrawal from this study.

12b. WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR

The study doctor has the right to end your participation in this study for any of the following reasons: If you become ill during the research, you may have to be discontinued, even if you would like to continue. The investigators, Drs. William Aronson and Zhaoping Li, will make this decision. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate. In addition, your study doctor may end your participation without regard to your consent.

13. NEW FINDINGS

We will tell you about new information that may affect your willingness to stay in the study.

14. IDENTIFICATION OF INVESTIGATORS

In the event that you have a question about the research or experience a research related injury or adverse reaction, please immediately contact one of the investigators on this study: Dr. Aronson at 310- 268-3446 or Dr. Li at 310-268-3528.

If you have an urgent question about the research or if you need to talk to someone urgently about the research after hours you may contact Dr. Aronson and Dr. Li through the UCLA page operator: 310-825-6301.

15. RIGHTS OF RESEARCH SUBJECTS

If you have any concerns regarding the following:

- the legitimacy of this study (whether it is a VA approved study);
- your rights as a research subject;
- how to express complaints regarding this research study; or
- what will happen in the event of a research-related injury;

you may contact your study doctor Dr. Aronson 310-268-3446 or research team member Dr. Li at 310-268-3528.

You may also contact the Associate Chief of Staff for Research and Development for the VAGLAHS at the VA Greater Los Angeles Healthcare System, 11301 Wilshire Blvd., Mail Code 151, Los Angeles, CA 90073. The telephone number is 310-268-4437.

AGREEMENT TO CONTINUE PARTICIPATION IN THE RESEARCH STUDY

Dr. William J. Aronson or his research Study coordinator, Sheryl Jeffery has explained the new study information for this research study to you. You have been told of the risks or discomforts and possible benefits regarding this new information. You have been told of other choices of treatment available to you. You have been given a the chance to ask questions and obtain answers.

You voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it. A copy of this signed consent will also be put in your medical record if applicable.

I agree to participate in this research study as has been explained in this document.		
Participant's Name	Participant's Signature	Date
Name of person obtaining consent	Signature of person obtaining consent	Date

RIGHTS OF HUMAN SUBJECTS IN MEDICAL EXPERIMENTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of any signed and dated written consent form used in relation to the experiment.
10. Be given an opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.