Participant Name: _____ Date: _____

Title of Study: Testosterone Plus Finasteride Treatment After Spinal Cord Injury

Principal Investigator: Joshua Yarrow, MS, PhD VA Facility: North Florida South Georgia VAMC

Principal Investigator for Multisite Study: Joshua Yarrow, MS, PhD

INTRODUCTION

You are being invited to take part in a research study that is being funded by the Department of Veterans Affairs. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive

Read the information below closely, and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part in this study, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

BACKGROUND AND PURPOSE

Why the Research is being done

With this research we hope to see if a drug therapy improves bone, muscle, fat mass, and markers of health in men with spinal cord injury. We also hope to see if this can be done without increasing prostate size. The drug therapy involves testosterone (the male hormone) and finasteride (a drug used to reduce prostate size). Both drugs are approved by the US Food and Drug Administration.

We will evaluate this drug therapy in men who have low testosterone and problems walking after spinal cord injury. The combination of testosterone plus finasteride has been shown to improve bone, muscle, fat, and some markers of health in other populations. It is not known if this therapy is effective in men with spinal cord injury.

We will screen up to 200 men with spinal cord injury to see who has low testosterone levels and walking problems. We will enroll up to 30 participants in the study.

The sponsor of this study is the Department of Veterans Affairs. The person in charge of the study is Dr. Joshua Yarrow.

Why you are Being Asked to Take Part

You are being asked to take part because you are a man over 18 years old who has a spinal cord injury.

DURATION OF THE RESEARCH

There are four parts to this study: screening, testing, treatment, and follow-up. If you choose to take part you will undergo screening to see if you qualify. Screening will take 1-2 days. If you qualify and decide to enroll, your participation in the project will last up to 18 months (1 year and 6 months). Testing will occur once every 1-3 months for the first 12 months of the study. At 1 month and 2 month visits testing will take about 2 hours. At baseline, 3 month, 6 month, 9

month, and 12 month visits, testing will take about 8 hours of your time, spread over 1-2 days. Treatment occurs during the first 12 months of the study. Treatment will take about 20 minutes per week of your time. Follow-up will occur during the last 6 months of the study. Follow-up phone calls will take about 10 minutes of your time per month. The 18 month study visit will take about 2 hours.

STUDY PROCEDURES

If you decide to take part in this study, this is what will happen:

Screening

You will undergo screening at the North Florida South Georgia VA Medical Center to see if you qualify to enroll. The screening is being done solely for the purposes of research and takes 1-2 days. Screening includes the following:

- We will perform a physical exam on you to see if you qualify. This will take about 1 hour.
- We will collect your health history and examine your medical chart to see if you qualify. This will take about 30 minutes.
- We will collect two blood samples from you (obtained between 6 AM and 11 AM and spaced at least 30 minutes apart). This is done to check your testosterone (male hormone) levels and other markers of health. Two samples are required to accurately measure your blood testosterone. The amount of blood taken at each time will be less than 7 teaspoons.
- Trained medical staff will perform a rectal exam to feel the shape of your prostate gland. They will also measure the size of your prostate with ultrasound. These tests will be done to see if your prostate gland is enlarged. Testosterone typically causes some prostate growth, while finasteride typically makes the prostate smaller. The combination of testosterone plus finasteride is expected to cause no change in the size of your prostate. These tests will take about 30 minutes. If a nodule (bump) is found on your prostate you will be referred for a prostate biopsy to see if you have prostate cancer, which is the standard of care. You can refuse to have a prostate biopsy. If you refuse to have a prostate biopsy or if you have prostate cancer you cannot continue with the study. You will be referred to VA Urology Service to discuss your options with your doctor if prostate cancer is found. If you do not have prostate cancer you can continue with the study.
- Trained medical staff will perform an electrocardiogram (EKG) exam of your heart. We will measure the activity in your heart by placing small sticky sensors onto your chest

and back. Specialized equipment will record your heart activity. This will take about 30 minutes.

- You will complete questionnaires about your past and current use of medications, nutritional status, your sexual function, and your cognitive and emotional status. In some cases, we will assist you with these forms. You are free to skip any questions that you do not want to answer. This will take about 1 hour.
- We will conduct tests to assess your physical and cognitive function. These include tests of your leg spasticity (muscle tightness), ability to perform daily tasks, balance, and walking ability. The tests of walking ability will be performed with and without brief cognitive tasks. Examples of the cognitive tasks include listing words starting with the letter "A", performing basic match calculations like continuously adding or subtracting 7, or other similar tasks. During the tests of walking ability, sensors may be taped or strapped to your head which allows us to estimate brain activity using a functional near infrared spectroscopy (fNIRS) device. fNIRS is a common device that uses harmless and non-invasive infrared light to estimate changes in hemoglobin (blood flow). This will take about 2 hours.

Testing

You will be invited to take part in this study if your testosterone is low and you are otherwise eligible. If you decide to take part in this study, you will be asked to undergo tests that are being done solely for the purposes of research. All testing will be done at the North Florida South Georgia VA Medical Center or at the University of Florida.

The tests that are listed in the Screening section (except for the physical exam, EKG, blood, and walk tests and rectal exam) will be repeated at three, six, nine, and twelve months of study treatment. The physical exam and EKG that are listed in the Screening section will be repeated at three, six, nine, twelve and 18 month study visits. The blood and walk tests that are listed in the Screening section will be repeated at one, two, three, six, nine, twelve, and 18 month study visits. The rectal exam that is listed in the Screening section will be repeated only at six and twelve months of study treatment.

Some other testing will be done at the start of the study (before you begin the study treatment) and after three, six, nine, and twelve months of the study treatment. These tests take 1-2 days to complete. These include the following:

- We will measure the muscle strength of your leg. You will perform a number of submaximal and maximal effort muscle contractions so that we may assess your muscle strength. Strength will be measured using specialized equipment in our lab. We will

also measure the activity in your muscles by taping small sensors onto the front and back of your legs. You will be provided with about one minute rest between each muscle contraction, or more if you feel tired. This will take about 2 hours.

- We will measure how fully you are able to contract your muscles. We will place small sticky pads near your hip and your knee that will send an electrical impulse through the muscle on your thigh. During this test you will feel a mild and very brief (fraction of a second) "shock". You might feel pain during the actual "shock", but this will go away in less than a second. We may perform up to about 25 of these stimulations. Sometimes we will stimulate while your muscles are at rest. Other times we will stimulate while you perform muscle contractions. This will take about 1 hour.
- We will assess your daily activity. You will complete a questionnaire about the types of physical activity you performed during the past week. We will assist you with these forms. You are free to skip any questions that you do not want to answer.

Other tests will be done at the start of the study (before you begin study treatment) and repeated after six and twelve months of the study treatment. These tests take 1-2 days to complete. These tests include:

- Trained medical staff will perform dual X-ray absorptiometry (DXA) scans on your whole body, thigh, hip, and lower back. A DXA scan is commonly known as a bone density scan. This is a type of x-ray that is used to measure body fat and the thickness of bones. You will be asked to lie on a table while a small amount of radiation passes through your body. The DXA scans will take about 45 minutes, during which you will need to lie still. You will be monitored during the DXA scans in case any problems occur.
- Trained medical staff will assess the size of your thigh muscle and other thigh tissue using magnetic resonance imaging (MRI). MRI is a test that allows doctors to look inside the body by using a scanner that sends out a strong magnetic field and radio waves. You will be asked to lie on a platform while a series of images (pictures) are taken from each leg. The MRI will take about 60 minutes, during which you will need to lie still. You will be monitored during the entire MRI scan in case any problems occur.

Treatment

You will be randomly assigned (much like the flip of a coin) to one of two treatment groups that receive:

- Placebo injection plus placebo pill for 12 months –OR–
- Testosterone injection plus finasteride pill for 12 months

A placebo is a substance that looks like and is given in the same way as an experimental treatment but contains no medicine. For example, an injection of sesame oil or a sugar pill. A placebo is used in research studies to show what effect a treatment has compared with taking nothing at all. If you are assigned to receive placebo, you will not receive the benefits of the testosterone plus finasteride, if there are any, nor will you be exposed to its risks, which are described below in the section titled "Possible Risks or Discomforts". Studies have shown, however, that about 1 in 3 persons who take a placebo do improve, if only for a short time.

You and the people conducting the study will not know whether you are receiving placebo or testosterone plus finasteride, but that information is available if it is needed. You will have a 50% chance of receiving testosterone plus finasteride and a 50% chance of receiving placebo. In the remainder of the description of what will be done, both testosterone plus finasteride and the placebo will be called "study treatment."

The study treatment is being done solely for the purposes of research. The study treatment will last for 12 months. The study treatment involves receiving an injection in the muscle of the thigh or buttock once weekly and taking a pill by mouth once daily. This will take about 10 minutes per week. You have the option to have the Study Nurse give you the weekly injection or to give the injection to yourself. If you choose to have the Study Nurse give the injection you will need to travel to the North Florida South Georgia VA Medical Center once weekly. If you choose to give yourself the injection you can do this at home and you will not need to travel to the VA weekly. During the study treatment you will also be asked to undergo tests that are discussed above in the Testing section.

During the study treatment you will also receive a weekly phone call from us. During the phone call we will ask you questions about your health. The phone call should take about 10 minutes per week. We will also check your medical record monthly during the study treatment to check your health. The phone call and medical records check are done solely for research purposes.

Study Completion and Follow-up

You will complete the study treatment after 12 months. You will receive a monthly phone call from us for 3 month after you complete the study treatment. During the phone call we will ask you questions about your health. The phone call should take about 10 minutes per month. We will also check your medical record once monthly after you complete the study. This is done to check your health. The phone call and medical records check are done solely for research purposes. We will also ask you to return 6 months after you complete the study so that we can assess walking tests and collect two blood samples from you (obtained between 6 AM and 11

AM and spaced at least 30 minutes apart). This is done to see if your walking function is maintained and to check your testosterone (male hormone) levels and other markers of health. Two samples are required to accurately measure your blood testosterone. The amount of blood taken at each time will be less than 7 teaspoons. You may receive a complete report of the findings of all tests after all participants have finished the study.

You may feel a depression of mood after stopping testosterone. If this occurs, the feeling should stop within a few weeks. If you are concerned by the loss of mood we will provide you with testosterone (at a lower dose than you received for the study treatment) for 4 weeks. This will ease the transition from stopping testosterone.

Summary

The research will be done at North Florida South Georgia VA Medical Center and the University of Florida. The research team members who you will interact with are Dr. Joshua Yarrow, a Study Coordinator, a Study Nurse, a Study Doctor, an Exercise Specialist, and other medical staff at the North Florida South Georgia VA Medical Center or the University of Florida. The screening will take about 1-2 days. If you qualify and decide to enroll, the study will last 1 year and 6 months. During the first 12 months you will take the study treatment which involves receiving a weekly injection into your muscle and taking a pill daily by mouth. You will undergo tests every 1-3 months while receiving the study treatment. You will also receive a weekly phone call from us while you are receiving the study treatment. After 12 months you will stop the study treatment. You will receive a monthly phone call from us for 3 months after stopping the study treatment. You will undergo physical exam, EKG, walking tests, and a blood test at 6 months after stopping the study treatment. We will monitor your safety and health while you take part in the study.

You do not have to participate in this research study if you do not want to. You can stop at any time without it affecting your medical care

Your Responsibilities Are To

- Take the study treatment as instructed.
- Keep your study appointments. If it you miss an appointment, please contact the research staff to reschedule as soon as you know you will miss the appointment.
- Perform testing and complete questionnaires as instructed.
- Complete phone calls as instructed.
- Keep the study treatment in a safe place for your use only and away from children.
- Tell the investigator or research staff if you change your mind about staying in the study.

- While participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from possible injury from things such as extra blood drawing, extra X-rays, or potential drug interactions. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this research, as well as that of the other studies.

POSSIBLE RISKS OR DISCOMFORTS

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

Blood Draw: The Study Nurse or a phlebotomist (someone who is trained in how to draw blood) will draw your blood to minimize risk. The risks of drawing blood from a vein include discomfort at the site of puncture, possible bruising and swelling around the puncture site, rarely an infection, and uncommonly faintness from the procedure. We may provide you with ice if bruising or swelling occur. You will be referred to the Study Doctor if an infection occurs.

Muscle Strength Testing: An Exercise Specialist (someone who is trained in how to conduct exercise tests) will perform muscle function tests to minimize this risk. As with any exercise, the risk of muscle soreness and muscle injury exists. We may provide you with ice if muscle pain occurs. You will be referred to the Study Doctor if muscle injury occurs.

DXA Scan: Trained medical staff will perform the DXA scans. The risks involved with DXA scan include exposure to ionizing radiation. Radiation exposure in this study is thought to be minor. However, the effects of radiation add up over the life span. Repeated exposures may increase risk of injury or disease. Examples would include x-rays taken for a broken bone. For comparison, this exposure is equivalent to 1 day of radiation exposure that people in the United States receive from natural background. The risk from radiation exposure of this magnitude is too small to measure directly and is considered to be low when compared with everyday risks. When deciding to enter this study you should consider previous and future potential exposures. This test is used routinely for medical care and is very safe for most people, but you will be monitored during all DXA scans in case any problems occur. We will provide you with a contact person if you would like more information about radiation exposure. The contact person is Kathleen Thomas, M.S., Radiation Safety Officer at North Florida South Georgia VA Medical Center, (XXX) XXX-XXXX.

MRI Scan: Trained medical staff will perform the MRI. An MRI is a test that allows doctors to look inside the body by using a scanner that sends out a strong magnetic field and radio waves. This test is used routinely for medical care and is very safe for most people, but you will be monitored during the entire MRI scan in case any problems occur. The risks of MRI are:

- The MRI scanner contains a very strong magnet. Therefore, you may not be able to have the MRI if you have any type of metal implanted in your body, for example, any pacing device (such as a heart pacer), any metal in your eyes, certain types of heart valves, brain aneurysm clips, or a spinal nerve stimulator. Someone will ask you questions about this before you have the MRI
- Because the MRI scanner acts like a large magnet, it could move metal objects in the MRI room, which could in the process possibly harm you. Standard precautions are in place to ensure loose metal objects are not allowed in the MRI room.
- There is not much room inside the MRI scanner. You may be uncomfortable if you do not like to be in close spaces ("claustrophobia"). During the MRI, you will be able to talk with the MRI staff through a speaker system. In the event of an emergencey, you can tell the staff to stop the scan.
- The MRI scan makes a loud hammering noise, which has caused hearing loss in a very small number of patients. You will be given earplugs to reduce the risk.

Study Treatment: Testosterone is a drug that is approved by the US Food and Drug Administration. It is similar to the male hormone that your body makes. Side effects observed in patients taking testosterone include increased hematocrit (red blood cells), increase of your blood prostate specific antigen (PSA), prostate growth, headache, increased blood pressure, acne, breast enlargement, breast tenderness, baldness, leg swelling, elevated liver enzymes, worsening of sleep apnea, decreased sperm count, peliosis hepatitis, hepatic neoplasms, thromboembolic events, and worsening of congestive heart failure. Rare side effects include a severe allergic reaction, pain or swelling at the injection site in the muscle, painful prolonged erection, stroke, or heart attack. It remains possible that testosterone may stimulate undiagnosed prostate cancer risk.

Finasteride is a drug that is approved by the US Food and Drug Administration to reduce the size of the prostate. It has been shown to cause a low rate of side effects, including: impotence, decreased interest in sex, reduced volume of semen, ejaculation disorder, breast enlargement, breast tenderness, breast cancer, or rash. Other unknown side-effects may result from finasteride treatment.

The risks of combining testosterone and finasteride include those listed above. Some studies have shown fewer prostate related side effects when combining testosterone and finasteride.

All drugs have the potential to cause allergic reactions. Allergic reactions may be mild to severe, and include the following symptoms: skin rash, itching, difficulty breathing, severe low blood pressure, and even death.

During this study you will receive physical exams, blood tests, and other medical tests to check your prostate, heart, and overall health. You will also complete questionnaires that are specific to sexual function. You will be removed from the study if you develop side effects that are considered severe or if the doctor feels it is within your best interest.

Prostate Exam: Trained medical staff will perform the prostate exam. The risks of the prostate exam and prostate ultrasound are relatively minor. These include occasional bleeding from the rectum, especially if hemorrhoids or anal fissures are present. In rare cases, you may feel lightheaded and faint. This feeling is called vasovagal syncope and is caused by fear or pain when the doctor inserts his finger into the rectum. If a nodule (bump) is found on your prostate you will be referred for a prostate biopsy to check if you have prostate cancer, which is the standard of care.

Data Security: As part of this study, your medical and health information and blood samples will be collected and stored. There is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. We will do everything reasonably possible to reduce this risk. Only persons involved with this study will have access to your information. All health and medical information will be kept on locked computers in locked offices. Blood samples will be stored without any information that can be used to identify you.

Financial Risk: You will be required to travel to the North Florida South Georgia VA Medical Center to take part in this study. You may also be required to take time off work to take part in this study. You will be reimbursed for gas or another form of travel to offset costs for the screening, baseline, 1 month, 2 month, 3 month, 6 month, 9 month, 12 month, and 18 month visits. You will receive compensation for your time involvement in the baseline, 3 month, 6 month, 9 month, and 12 month visits. Any overnight stay that is required for you to take part in the screening, baseline, 1 month, 2 month, 3 month, 6 month, 9 month, 12 month or 18 month visits will be provided at no cost to you.

You will not be reimbursed for gas or for any other form of travel for you to attend weekly visits for the Study Nurse to give you an injection. You will not receive compensation to attend weekly

visits for the Study Nurse to give you an injection.

Other Risks: Participation in more than one research study may further increase the risks to you. If you are already enrolled in another research study, please inform the person reviewing this consent form with you before enrolling in this or any other research study.

Throughout the study, we will notify you of new information that might affect your decision to remain in the study. If you wish to discuss the information above or any discomforts you may feel, you may ask questions now or call the Principal Investigator or another contact person listed on page 12 of this document.

Risks of the usual care you receive are not risks of the research. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

POTENTIAL BENEFITS

We cannot promise that you will get any benefits from taking part in this research study. However, possible benefits may include improved physical function, improved bone strength, feeling stronger, feeling more energetic, and reduced body fat. The information we gather will also help us find out whether testosterone (male hormone) replacement plus finasteride improves physical function, improves bone strength, and reduces body fat in men with spinal cord injury. This may result in men with spinal cord injury being able to function better.

ALTERNATIVES TO PARTICIPATING IN THIS RESEARCH

You may choose not to participate in this study. If this is your decision, there are other choices. Your doctor may choose to treat you with any form of testosterone (gels, patches, or injections). Your doctor may also choose to treat you with finasteride. You may discuss these options with your doctor.

CONFIDENTIALITY

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

We will carry informed consent forms in a locked bag. We will keep your study records locked in filing cabinets in a secure VA building and on computers protected with a secret password, behind the VA firewall. Only staff that has a need to know will have access to your record. We are collecting your Social Security number in order to find information about your past and current health in your medical record. We will keep these records in a locked file cabinet in a secure VA building and on computers protected with a secret password, behind the VA firewall.

Information about you will be combined with information from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you.

The information we collect during this study will be kept confidential. We will include information about your study participation in your medical record. There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, other study monitors, and the US Food and Drug Administration may look at or copy portions of records that identify you.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

COSTS TO PARTICIPANTS AND PAYMENT

Costs to Participants*:* You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

You may be required to take time away from work to take part in this study. You will be required to travel to the North Florida South Georgia VA Medical Center to take part in this study.

Payment Offered for Participation: You will be offered payment to compensate you for the time it takes you to complete the baseline, 3 month, 6 month, 9 month, and 12 month testing sessions. You will also be offered reimbursement for transportation to the North Florida South Georgia VA Medical Center for the screening, baseline, 1 month, 2 month, 3 month, 6 month, 9 month, 12 month, and 18 month testing sessions. Any overnight lodging that is required for you

to take part in the screening, baseline, 1 month, 2 month, 3 month, 6 month, 9 month, 12 month, and 18 month testing sessions will be provided at no cost to you.

Specifically, we will pay you:

- Up to $400 for taking part in this study. This payment will be divided evenly among the 5 testing sessions. This means you will be issued $80 after you complete each of the following testing sessions: baseline, 3 month, 6 month, 9 month, and 12 month. If you withdraw or are removed from the study, you will receive a pro-rated amount based on the number of sessions you took part in.
- Up to $0.415 per mile of travel for round-trip travel between your home and the North Florida South Georgia VA Medical Center. Travel reimbursement will be given to you for the screening, baseline, 1 month, 2 month, 3 month, 6 month, 9 month, 12 month, and 18 month testing sessions. You will receive reimbursement for each testing session you attend. If you withdraw or are removed from the study, you will not receive any additional travel reimbursement for the study.
- Any overnight lodging that is required for you to take part in the screening, baseline, 1 month, 2 month, 3 month, 6 month, 9 month, 12 month, or 18 month testing session for this study will be provided at no cost to you.

Your compensation for participation in this research study will come from the VA Finance Office, who will issue payment to you by direct deposit to your bank account. If it is not possible for you to receive payment by direct deposit, you may have payment sent to a pre-paid debit card. If you use a pre-paid debit card you will be required to maintain this card throughout the study as all study payments will be deposited to the card. The study team will provide you with additional information regarding electronic funds transfers.

You may be responsible for paying income taxes on any payments provided by the study. Any payment made to you on a VA-funded study, regardless of amount, has to be reported to the Internal Revenue Service (IRS) because the payment system cannot distinguish payment from reimbursement for expenses.

If you have any outstanding debts to the government (such as back taxes, child support arrears, or defaulted school loans), the government can garnish this payment to offset your outstanding debt

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY

The Principal Investigator in Gainesville: Dr. Joshua Yarrow at (XXX) XXX-XXXX.
The Local Site Investigator in Tampa: Dr. Kevin White at (XXX) XXX-XXXX ext. XXXX.

AFTER HOURS (EVENINGS, WEEKENDS, AND EMERGENCIES)

The Principal Investigator in Gainesville: Dr. Joshua Yarrow at (XXX) XXX-XXXX .
The Local Site Investigator in Tampa: Dr. Kevin White at (XXX) XXX-XXXX ext. XXXX.

Emergency and ongoing medical treatment will be provided as needed.

If you experience an injury or illness as a result your participation in this research study, all medical treatment considered necessary by your doctor (emergency as well as medical treatment beyond emergency) will be provided by the VA. There will be no cost to you, unless you fail to follow the directions of the study procedures. Care will be provided at a VA medical facility unless the VA medical facility is not capable of providing the care. If this occurs, you will be treated by a private facility or physician and the VA will pay the private facility or physician for the reasonable cost of your care. In some cases, the VA may approve private care for a non-veteran.

If you do not follow the study procedures, you may be treated by the VA on the basis of your Veteran's eligibility. The VA can only provide limited care at your expense if you are not a Veteran and have not followed study procedures.

In the event of a research-related injury, or if you have questions about any discomforts that you feel while participating in this study, or if you experience an adverse reaction, please immediately contact the following individuals:

- Principal Investigator, Dr. Joshua Yarrow at (XXX) XXX-XXXX during the day or at (XXX) XXX-XXXX after business hours

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PI/SC Approval Date: October 30, 2018

LSI Approval Date: NA

LSI Verification Date: NA

- Local Site Investigator, Dr. Kevin White at (XXX) XXX-XXXX ext. XXXX during the day or at (XXX) XXX-XXXX after business hours.

If you seek emergency hospitalization in a private hospital because you are unable to come to the VA, have your family or a friend contact your study doctor so that the VA can coordinate care with the private hospital.

You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

PARTICIPATION IS VOLUNTARY

It is up to you to decide whether or not to take part in this study. If you decide to take part, you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient. If you are a VA employee, your refusal to take part in the study will in no way influence your employment, ratings, or subsequent recommendations. If you are a student, your refusal to take part will in no way influence subsequent recommendations or academic progress.

There are no consequences if you decide to withdraw from the study. If you decide to stop participating after the study procedures begin, simply tell the study staff. You will be withdrawn without any penalty to you. We may continue to use any information we have already collected. We may not collect any more information except information from public records. If you withdraw from the study, blood samples that have already been used cannot be withdrawn.

RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION

You may be withdrawn from the study without your consent for the following reasons:

- If the doctor believes, for any reason, that it is within your best interest
- If you develop side effects that are considered dangerous
- If you refuse to accept the study treatment
- If you fail to return for follow-up as recommended by your study doctor or fail to follow the study doctor's instructions
- If you refuse to have tests that are needed to find out whether study treatments are safe and effective
- If you require treatment with drugs that are not allowed in the study

- If other causes prevent continuation of the research study
- The Food and Drug Administration, the VA Central Institutional Review Board, or the Data and Safety Monitoring Board decides to end the study

The decision of the Principal Investigator to withdraw you from the study will not affect your medical care. If you are withdrawn from the study, you will receive a monthly phone call from us for 3 months. During the phone call we will ask you questions about your health. The phone call should take about 10 minutes per month. We will also check your medical record monthly for 3 months. This is done to check your health.

PERSONS TO CONTACT ABOUT THIS STUDY

If you have any questions, complaints, or concerns about the research, you should contact the following people:

- The Principal Investigator in Gainesville, Dr. Yarrow at (XXX) XXX-XXXX
- The Local Site Investigator in Tampa, Dr. White at (XXX) XXX-XXXX ext. XXXX
- The Patient Advocate, Michelle Howard at (XXX) XXX-XXXX ext. XXXXXX

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

SIGNIFICANT NEW FINDINGS

Sometimes during the course of a research study, new information becomes available about the treatment that is being studied that might change a person's decision to stay in the study. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw from the study, your research doctor will arrange for your medical care to continue. If you decide to continue in the study, you might be asked to sign an updated informed consent form. Your research doctor could also decide it to be in your best interests to withdraw you from the study. If so, he will explain the reasons and arrange for your usual medical care to continue.

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: October 30, 2018

LSI Approval Date: NA

LSI Verification Date: NA

Participant Name: _____ Date: _____

Title of Study: Testosterone Plus Finasteride Treatment After Spinal Cord Injury

Principal Investigator: Joshua Yarrow, MS, PhD VA Facility: NF/SG VHS

Principal Investigator for Multisite Study: Joshua Yarrow, MS, PhD

PAYMENT TO INVESTIGATORS

The investigators involved in this study will receive salary from the Department of Veterans Affairs because this study is part of their normal job duties. No other payments are being provided to the investigators.

FUTURE USE OF DATA AND RE-CONTACT

Data collected during this study, including your health information and outcomes of study procedures, will be retained after completion of the study. Study records will be stored in locked filing cabinets in a secure VA building and on computers protected with a secret password, behind the VA firewall. Only staff that has a need to know will have access to your records.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The Principal Investigator (Dr. Joshua Yarrow), the Study Nurse, or the Study Coordinator has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, 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.

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

SUBJECT'S IDENTIFICATION

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: October 30, 2018

LSI Approval Date: NA

LSI Verification Date: NA