

## MALE TESTOSTERONE CONSENT FORM-WHITESBORO FAMILY MEDICAL CLINIC

Bio-identical testosterone is biologically identical to the testosterone hormone you make in your own body. Testosterone is derived from the testicles (primarily) and adrenal glands (secondarily) prior to andropause.

Testosterone supplementation, in medical research, has been shown to improve fatigue, exercise intolerance, muscle tone, libido, weight, and other conditions. It has been shown in research studies to decrease the risk of cardiovascular disease, diabetes, metabolic syndrome, and prostate cancer.

Though laboratory assays can support a diagnosis of testosterone deficiency, they should not be used to exclude it as there are multiple problems in the measurement of testosterone (ex. dietary intake, sexual activity, sample storage variables, circadian variations). Greater reliance on the clinical features and consideration of symptoms is suggested as an appropriate tool in treating men with testosterone therapy. The generally accepted cutoff for low "normal" serum total testosterone is 300 ng/dL. It is reasonable to prescribe testosterone to a man who has symptoms of low testosterone and to expect testosterone values that are supraphysiologic after treatment.

All testosterone use in men with a serum level of more than 300 ng/dL is considered "off label use." Off-label use refers to the use of any medication for something other than its FDA (Food and Drug Administration) approval. Many medications prescribed in the US are prescribed for off-label use. The off-label use of testosterone therapy has not been evaluated by the FDA and any claims of benefit are purely educated opinions that come from consideration of various medical research studies.

Hormone pellet production is highly FDA regulated; however, the testosterone pellet insertion procedure is not an FDA approved procedure for hormone replacement in the pellet doses we use for men (200 mg pellet).

Goals for treatment will be discussed at each appointment. If goals are met, then maintenance doses will be discussed. If the treatment is not as effective as anticipated, it might be discontinued; at that time, alternative therapies will be discussed. You are welcome to seek a second opinion or a specialist consultation.

**SIDE EFFECTS:** Side effects of testosterone will be managed clinically and individually. There have been no reported irreversible side effects of testosterone noted in the literature to date.

Potential side effects of testosterone therapy may include, but are not limited to:

Hyper-sexuality (overactive libido), increased hemoglobin and hematocrit (erythrocytosis), acne, increase in body/facial hair growth, hair loss/thinning and virilization, testicular shrinkage, and reduction of sperm production that may take up to a year or more to normalize to baseline.

Potential side effects of pellet insertion may include, but not limited to: Bleeding, bruising, swelling, and pain; extrusion of pellets; infection or abscess formation; seroma formation; scarring at insertion site; keloid scar. Surgical risks are the same as for any minor medical procedure.

Potential side effects of intramuscular injection may include, but not limited to: Pain or redness at the injection site.

## References:

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Evidence linking testosterone therapy to the development of prostate cancer has not been established. In fact, a meta-analysis of 197 studies demonstrated that testosterone administration does not increase the risk of prostate cancer. High testosterone does not predispose a man to prostate cancer and low testosterone is not protective. There is some risk, even with natural testosterone therapy, of stimulating an *existing* prostate cancer to grow more rapidly. Following the American Urological Association recommendations for the evaluation and management of testosterone deficiency, a prostate specific antigen blood test is to be done before starting testosterone pellet therapy in men over 40 and annual labs may be required at the discretion of your healthcare provider. If there is concern about possible prostate cancer, additional testing and/or follow up with specialist may be required.

**CONSENT FOR TREATMENT:** I have been informed that I may experience any of the complications related to testosterone replacement and if choosing pellet therapy, complications of the pellet placement procedure. Periodic adjustments are required to fine tune the treatment with this type of medication. Periodic blood tests are necessary to determine if the dose needs to be adjusted. I understand that testosterone supplementation is available in several forms including cream, oral formulation, injections, and subcutaneous pellets. I understand that I am consenting to testosterone therapy for off label use of my symptoms if my baseline serum testosterone levels are over 300ng/dl. I understand the hormone pellet procedure is not FDA approved.

**AFTERCARE:** I agree to immediately report to my practitioner's office any adverse reaction or problems that might be related to my therapy. Potential complications have been explained to me and I agree that I have received information regarding those risks, potential complications and benefits, and the nature of hormone and other treatments and have had all my questions answered. Furthermore, I have not been promised or guaranteed any specific benefits from the administration of hormone therapy. I accept these risks and benefits, and I consent to the treatment with testosterone in the agreed upon delivery mechanism with a dosage regime discussed thoroughly by my hormone provider.

I have read and understand this document in its entirety and have been given the opportunity to ask questions concerning my care. I consent to testosterone therapy and if pellets are desired, to the subcutaneous hormone pellet insertion. This consent is ongoing for this and all future testosterone replacement of all delivery mechanisms.

**Print Name:** \_\_\_\_\_

**Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_

## Whitesboro Family Medical Clinic-Male Post Insertion Instructions

- Your insertion site has been covered with two layers of bandages. Remove the outer pressure bandage any time after 3 to 4 hours. It must be removed as soon as it gets wet. You may replace it with a bandage to catch any anesthetic that may ooze out. The inner layer is either waterproof foam tape or steri-strips. They should be removed in **3 days**. If the tape or steri-strip comes off, you may replace it with a band-aid.
- Do not take tub baths or get into a hot tub for the next **3 days**. You may shower but do not scrub the site until the incision is well healed (about 7 days).
- No major exercises for the incision area for the next **7 days**, this includes running, riding a horse, etc.
- The sodium bicarbonate in the anesthetic may cause the site to swell for 1-3 days. This is normal.
- The insertion site may be uncomfortable for up to 2-3 weeks. If there is itching or redness you may take Benadryl for relief, 50mg. orally every 6 hours. Caution this can cause drowsiness!
- You may experience bruising, swelling, and /or redness of the insertion site which may last from a few days up to 2-3 weeks.
- You may notice some pinkish or bloody discoloration of the outer bandage. This is normal.
- If you experience bleeding from the incision, apply firm pressure for 5 minutes.
- Please call if you have bleeding (not oozing) or pus coming out of the insertion site that is not relieved by pressure.

### Reminders

- **New patients-VERY important!**
  - Please go for your post-insertion blood work 4 weeks after your initial pellet insertion.
  - Please schedule a lab review appointment 5 weeks after your initial pellet insertion so we can review your post-insertion lab results. There is no charge for the additional pellet boost.
- On average, males need pellet insertions every **5 months** after their initial insertion.
- Please call to make an appointment for re-insertion as soon as symptoms that were relieved from the pellets start to return. The charge for the second visit will be only for the insertion and not a consultation.

**Print Name**

**DOB**

**Signature**

**Date**

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# WHITESBORO FAMILY MEDICAL AMS MALE Checklist - BEFORE HRT

Place an "X" for EACH symptom you are currently experiencing. *Please mark only ONE box.*  
For symptoms that do not apply, please mark NONE.

	SCORE:	None 1	Mild 2	Moderate 3	Severe 4	Extremely Severe 5
1. <b>Decline in your feeling of general well-being</b> (general state of health, subjective feeling)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. <b>Joint pain and muscular ache</b> (lower back pain, joint pain, pain in a limb, general back ache)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. <b>Excessive sweating</b> (unexpected/sudden episodes of sweating, hot flushes independent of strain)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. <b>Sleep problems</b> (difficulty in falling asleep difficulty in sleeping through, waking up early and feeling tired, poor sleep, sleeplessness)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. <b>Increased need for sleep, often feeling tired</b>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. <b>Irritability</b> (feeling aggressive, easily upset about little things, moody)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. <b>Nervousness</b> (inner tension, restlessness, feeling fidgety)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. <b>Anxiety</b> (feeling panicky)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. <b>Physical exhaustion / lacking vitality</b> (general decrease in performance, reduced activity, lacking interest in leisure activities, feeling of getting less done, of achieving less, of having to force oneself to undertake activities)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. <b>Decrease in muscular strength</b> (feeling of weakness)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. <b>Depressive mood</b> (feeling down, sad, on the verge of tears, lack of drive, mood swings, feeling nothing is of any use)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. <b>Feeling that you have passed your peak</b>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. <b>Feeling burnt out, having hit rock-bottom</b>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. <b>Decrease in beard growth</b>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. <b>Decrease in ability/frequency to perform sexually</b>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. <b>Decrease in the number of morning erections</b>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. <b>Decrease in sexual desire/libido</b> (lacking pleasure in sex, lacking desire for sexual intercourse)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please share any additional comments about your symptoms you would like to address. \_\_\_\_\_

Do you have cold hands and feet?  Yes  No      Do you have daily bowel movements?  Yes  No

Do you have gas, bloating or abdominal pain after eating?  Yes  No

Please select your WEEKLY Activity Level based on this criteria → *Physical activity that accelerates heart rate / Breathlessness*  
 0-1 day per week (Low)     2-3 days per week (Average)     More than 3 days per week (High)

Please list any prior hormone therapy? \_\_\_\_\_

Recent PSA: \_\_\_\_\_ Recent Digital Rectal Exam (Date): \_\_\_\_\_ Normal / Abnormal  
 History of Prostate problems or Biopsy. If so, please provide details. \_\_\_\_\_

**FOR OFFICE USE ONLY**

CHART ID: \_\_\_\_\_ DOB: \_\_\_\_\_ APPT DATE: \_\_\_\_\_

Name: \_\_\_\_\_ Today's Date: \_\_\_\_\_  
(Last) (First) (Middle Initial)

Date of Birth: \_\_\_\_\_ Age: \_\_\_\_\_

### MEDICAL HISTORY

Height: \_\_\_\_\_ Weight: \_\_\_\_\_ Last Menstrual Period: \_\_\_\_\_ Hysterectomy? ( ) No ( ) Partial ( ) Full

Do you smoke? ( ) Yes ( ) No ( ) Quit How much? \_\_\_\_\_ How often? \_\_\_\_\_ Age started? \_\_\_\_\_

Do you drink alcohol? ( ) Yes ( ) No ( ) Quit How much? \_\_\_\_\_ How often? \_\_\_\_\_ Age started? \_\_\_\_\_

Any known drug allergies: ( ) Yes ( ) No If yes please explain: \_\_\_\_\_

Nutritional/Vitamin Supplements: \_\_\_\_\_

Current Hormone Replacement Therapy: \_\_\_\_\_ Past HRT: \_\_\_\_\_

Other Pertinent Information: \_\_\_\_\_

Do you have a personal history of? Check all that apply.

#### Preventative Medical Care:

- ( ) Medical/GYN Exam in the last year
- ( ) Mammogram in the last 12 months
- ( ) Bone Density in the last 12 months
- ( ) Pelvic ultrasound in the last 12 months

#### High Risk Past Medical/Surgical History:

- ( ) Breast Cancer
- ( ) Uterine Cancer
- ( ) Ovarian Cancer
- ( ) Hysterectomy with removal of ovaries
- ( ) Hysterectomy only
- ( ) Oophorectomy Removal of Ovaries
- ( ) Prostate Cancer

#### Birth Control Method:

- ( ) Menopause
- ( ) Hysterectomy
- ( ) Tubal Ligation
- ( ) Birth Control Pills
- ( ) Vasectomy
- ( ) Other: \_\_\_\_\_

#### Medical Illnesses:

- ( ) High blood pressure
- ( ) Heart bypass
- ( ) High cholesterol
- ( ) Hypertension
- ( ) Heart Disease
- ( ) Stroke and/or heart attack

- ( ) Blood clot and/or a pulmonary emboli
- ( ) Arrhythmia
- ( ) Any form of Hepatitis or HIV
- ( ) Lupus or other auto immune disease
- ( ) Fibromyalgia
- ( ) Trouble passing urine or take Flomax or Avodart
- ( ) Chronic liver disease (hepatitis, fatty liver, cirrhosis)
- ( ) Diabétes
- ( ) Thyroid disease
- ( ) Arthritis
- ( ) Depression/anxiety
- ( ) Psychiatric Disorder
- ( ) Cancer Type: \_\_\_\_\_ Year: \_\_\_\_\_

\_\_\_\_\_  
PRINT NAME

\_\_\_\_\_  
SIGNATURE

\_\_\_\_\_  
DATE

**WHITESBORO FAMILY MEDICALCLINIC  
EVEXIAS Fee Acknowledgment**

Female Hormone Pellet Insertion Fee	\$325
Male Hormone Pellet Insertion Fee	\$550
Male Hormone Pellet Insertion Fee (> 2000mg)	\$650

\_\_\_\_\_  
**Print Name**

\_\_\_\_\_  
**Signature**

\_\_\_\_\_  
**Date**

**We accept the following forms of payment**

*American Express, Master Card, Visa, Discover, Checks, Cash*