

FEMALE TESTOSTERONE AND/OR ESTRADIOL CONSENT FORM WHITESBORO FAMILY MEDICAL

Bio-identical hormones are concentrated hormones biologically identical to the hormones you make in your own body. Estrogen, progesterone, and testosterone are derived from the female ovaries (primarily) and adrenal glands (secondarily) prior to menopause.

Testosterone is a hormone produced by the ovaries and adrenal glands in women. In the medical research, testosterone supplementation in women has been shown to improve fatigue, exercise intolerance, muscle tone, libido, weight, depression, anxiety, and other conditions.

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 women with testosterone therapy. There is no generally accepted "normal" level of testosterone for women. It is reasonable to prescribe testosterone to a woman who has symptoms of low and to expect testosterone values that are supraphysiologic after treatment.

All testosterone use in women is considered "off-label." 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.

Regarding hormone pellets, the production of the pellet is highly FDA regulated; however, the pellet insertion procedure is not an FDA approved procedure for hormone replacement.

Treatment goals 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, and alternative therapies will be discussed. You are welcome to seek a second opinion or a specialist consultation.

The safety of hormone therapy during pregnancy cannot be guaranteed. Notify your provider if you are pregnant, suspect that you are pregnant or are planning to become pregnant during this therapy. Continuous exposure to testosterone during pregnancy may cause adverse effects in the fetus.

My birth control method is (please check):

Abstinence Birth Control Pill Hysterectomy IUD Menopause Tubal Ligation

Vasectomy Other

SIDE EFFECTS: Side effects of hormone therapy will be managed clinically and individually. There have been no reported irreversible side effects of hormone replacement therapy noted in the literature.

Potential side effects of pellet insertion procedure 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.

Potential side effects of the hormones may include, but are not limited to:

Estradiol Related: Dysfunctional uterine bleeding; growth of estrogen dependent tumors and breast tenderness. Oral formulations of estrogen have been shown to have a slight increased risk of blood clots, with a greater risk to smokers and overweight/obese persons. Non oral modalities of estradiol have not shown risk of blood clots.

Recent studies regarding risk of breast cancer in women taking menopausal hormones including estrogens have shown that estrogen and/or estradiol do not increase the risk of breast cancer or breast cancer recurrence. However, if a patient has an undiagnosed estrogen/hormone dependent cancer, a possible risk of accelerated growth may occur. For this reason, mammograms, according to current clinical guidelines, are recommended as a baseline prior to estradiol therapy.

Every patient has a right to refuse diagnostic mammogram. If refused, you will be required to sign a mammogram waiver before receiving hormone therapy. If you have a uterus and are on estradiol therapy, oral micronized progesterone (prescription) must be taken daily for protection against uterine cancer.

Testosterone Related: Hyper-sexuality (overactive libido), increased hemoglobin and hematocrit (erythrocytosis), acne, increase in body/facial hair growth, abnormal menstrual cycles, hair loss/thinning and virilization, voice changes or abnormal growth of the female genitals.

CONSENT FOR TREATMENT: I have been informed of all of options for hormone therapies and that I may experience any of the complications related to hormone replacement therapy and to the pellet procedure, should I proceed with that 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 hormone therapies are available in many forms including creams, patches, injections, and oral medications. I understand that I am consenting to testosterone therapy for off label use of my symptoms. 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 if pursuing pellet therapy, I consent to the insertion of hormone pellets with a dosage regime discussed thoroughly by my hormone pellet 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 hormone replacement therapy and if pertinent to my agreed upon treatment plan, subcutaneous hormone pellet insertion. This consent is ongoing for this and all future management of hormone therapies and subcutaneous hormone pellet insertions.

Print Name

Signature

Date

Whitesboro Family Medical Female 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 **4 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, females need pellet insertions every **4 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 _____

MRS FEMALE Checklist - BEFORE HRT WHITESBORO FAMILY MEDICAL CLINIC

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. Hot flashes, sweating (episodes of sweating)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Heart discomfort (unusual awareness of heart beat, heart skipping, heart racing, tightness)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Sleep problems (difficulty in falling asleep, difficulty in sleeping through the night, waking up early)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Depressive mood (feeling down, sad, on the verge of tears, lack of drive, mood swings)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Irritability (feeling nervous, inner tension, feeling aggressive)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Anxiety (inner restlessness, feeling panicky)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Physical and mental exhaustion (general decrease in performance, impaired memory, decrease in concentration, forgetfulness)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Sexual problems (change in sexual desire, in sexual activity and satisfaction)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Bladder problems (difficulty in urinating, increased need to urinate, bladder incontinence)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Dryness of vagina (sensation of dryness or burning in the vagina, difficulty with sexual intercourse)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Joint and muscular discomfort (pain in the joints, rheumatoid complaints)		<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?

FOR OFFICE USE ONLY

CHART ID: _____ **DOB:** _____ **APPT DATE:** _____

WHITESBORO FAMILY MEDICAL-WHAT MIGHT OCCUR (FOR FEMALES ONLY)

A significant hormonal transition will occur in the first 3-6 weeks after beginning your BHRT regime. Therefore, certain changes might develop that can be bothersome.

FLUID RETENTION: Testosterone stimulates the muscle to grow and retain water, which may result in a weight change of two to five pounds. This is only temporary. This happens frequently with the first insertion, and especially during hot, humid weather conditions.

SWELLING OF THE HANDS & FEET: This is common in hot and humid weather. It may be treated by drinking lots of water, reducing your salt intake, taking cider vinegar capsules daily, (found at most health and food stores) or by taking a mild diuretic, which the office can prescribe.

UTERINE SPOTTING/BLEEDING: This may occur in the first few months after an insertion, especially if you have been prescribed progesterone and are not taking properly: i.e. missing doses, or not taking a high enough dose. Please notify the office if this occurs. Bleeding is not necessarily an indication of a significant uterine problem. More than likely, the uterus may be releasing tissue that needs to be eliminated. This tissue may have already been present in your uterus prior to getting pellets and is being released in response to the increase in hormones.

MOOD SWINGS/IRRITABILITY: These may occur if you were quite deficient in hormones. They will disappear when enough hormones are in your system.

FACIAL BREAKOUT: Some pimples may arise if the body is very deficient in testosterone. This lasts a short period of time and can be handled with a good face cleansing routine, astringents and toner. If these solutions do not help, please call the office for suggestions and possibly prescriptions.

HAIR THINNING: Is VERY rarely caused by the addition of hormones, including testosterone. More often a woman's hair has been thinning or dormant for a long time because of the lack of hormones. Once hormone therapy begins, the hair follicles wake up and begin to do their job- shed old hair and grow new hair. This can last several weeks and be very disconcerting, but rest assured it is normal and is a sign of healthy metabolism. Supplements and over the counter topical Rogaine helps slow down the shed stage and may be helpful. Your provider may also have other topical options available during this transition to lessen the shedding.

HAIR GROWTH: Testosterone may stimulate some growth of hair on your chin, chest, nipples and/or lower abdomen. This tends to be hereditary. You may also have to shave your legs and arms more often. Dosage adjustment may reduce the problem but rarely will eliminate it.

I acknowledge that I have received a copy and understand the instructions on this form.

Name (Print Legibly)

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