Pelosi Medical Center
BHRT PELLET INSERTION CONSENT - MALE

My physician/practitioner has recommended testosterone therapy delivered by a pellet inserted under my skin for treatment of symptoms I am experiencing related to low testosterone levels. The following information has been explained to me prior to receiving the recommended testosterone therapy.

OVERVIEW

Bioidentical testosterone is a form of testosterone that is biologically identical to that made in my own body. The levels of active testosterone made by my body have decreased, and therapy using these hormones may have the same or similar effect(s) on my body as my own naturally produced testosterone. The pellets are a delivery mechanism for testosterone, and bioidentical hormone replacement therapy using pellets has been used since the 1930's. There are other formulations of testosterone replacement available, and different methods can be used to deliver the therapy. The risks associated with pellet therapy are generally similar to other forms of replacement therapy using bioidentical hormones.

RISKS/COMPLICATIONS

Risks associated with pellet insertion may include: bleeding from incision site, bruising, fever, infection, pain, swelling, pellet extrusion which may occur several weeks or months after insertion, reaction to local anesthetic and/or preservatives, allergy to adhesives from bandage(s), steri strips or other adhesive agents.

Some individuals may experience one or more of the following complications: acne, anxiety, breast or nipple tenderness or swelling, insomnia, depression, mood swings, fluid and electrolyte disturbances, headaches, increase in body hair, fluid retention or swelling, mood swings or irritability, rash, redness, itching, lack of effect (typically from lack of absorption), transient increase in cholesterol, nausea, retention of sodium, chloride and/or potassium, weight gain or weight loss, thinning hair or male pattern baldness, increased growth of prostate and prostate tumors which may or may not lead to worsening of urinary symptoms, hypersexuality (overactive libido) or decreased libido, erectile dysfunction, painful ejaculation, ten
to fifteen percent shrinkage in testicular size, and/or significant reduction in sperm production, increase in neck circumference, overproduction of estrogen (called aromatization) or an increase in red blood cell formation or blood count (erythrocytosis). The latter can be diagnosed with a blood test called a complete blood count (CBC). This test should be done at least annually. Erythrocytosis can be reversed simply by donating blood periodically, but further workup or referral may be required if a more worrisome condition is suspected.

All types of testosterone replacement can cause a significant decrease in sperm count during use. Pellet therapy may affect sperm count for up to one year. If you are planning to start or expand your family, please talk to your provider about other options.

Additionally, there is some risk, even when using bioidentical hormones, that testosterone therapy may cause existing cases of prostate cancer to grow more rapidly. For this reason, a prostate specific antigen blood test (PSA) is recommended for men ages 55-69 before starting hormone therapy, even if asymptomatic. Testing is also recommended for younger individuals considered high risk for prostate cancer. The test should be repeated each year thereafter. If there is any question about possible prostate cancer, a follow-up referral to a qualified specialist for further evaluation may be required.

CONSENT FOR TREATMENT:

I agree to immediately report any adverse reactions or problems that may be related to my therapy to my physician or health care provider's office, so that it may be reported to the manufacturer. Potential complications have been explained to me, and I acknowledge that I have received and understand this information, including the possible risks and potential complications and the potential benefits. I also acknowledge that the nature of bioidentical therapy and other treatments have been explained to me, and I have had all my questions answered.

I understand that follow-up blood testing will be necessary four (4) weeks after my initial pellet insertion and then at least one time annually thereafter. I also understand that although most patients will receive the correct dosage with the first insertion, some may require dose changes.

I understand that my blood tests may reveal that my levels are not optimal which would mean I may need a higher or lower dose in the future. Furthermore, I have not been promised or guaranteed any specific benefits from the insertion of testosterone pellets. I have read or have had this form read to me.

I accept these risks and benefits, and I consent to the insertion of testosterone pellets under my skin performed by my provider. This consent is ongoing for this and all future insertions in this facility until I am no longer a patient here, but I do understand that I can revoke my consent at any time. I have been informed that I may experience any of the complications to this procedure as described above.

I have read or have had this form read to me.

_____	___/___/___	_____	___/___/___	_____	__/___/__
Patient Signature	Date	Witness Signature	Date	Surgeon Signature	Date