

## INFORMED CONSENT FOR HORMONE PELLET THERAPY (MALE)

Patient Name: \_\_\_\_\_ Today's Date: \_\_\_\_\_

So that you can make an informed decision, you have the right to be informed about your condition, the recommended treatment, the benefits and potential risks of treatment, alternatives to the recommended treatment, and the risks of not receiving treatment at all.

Based on symptoms, lab work, and physical examination, you have been diagnosed with a hormone deficiency. Dr. Thomas is recommending treatment with low-dose, compounded, prescription natural (non-synthetic) hormone replacement therapy. This is also known as bio-identical hormone replacement therapy. It consists of plant-derived hormones that have the same chemical and molecular structure as hormones produced by the body.

The available hormone delivery methods include pills, sublingual (medication that dissolves under the tongue), injections, topical (creams, gels, patches), and subcutaneous pellets. It is Dr. Thomas's professional opinion that subcutaneous pellets are superior because of the ease of use, lack of cross contamination, and the ability to maintain steady and healthy physiologic levels in both the blood and tissues of the body.

The potential benefits of treatment are numerous and may include increased energy levels; increased sense of well-being ("zest for life"); increased sex drive and satisfaction; stronger erections; improved mental sharpness, concentration, and memory; improved sleep; decreased sagging of the skin; decreased body fat; increased muscle mass and strength; better response to diet and exercise; more stable moods (less irritability and grumpiness); less anxiety and depression; less joint pain and muscle aches; improved flexibility and mobility; increased bone density; fewer and less intense migraine headaches; stronger immune system; lower cholesterol levels; improved blood sugar levels; increased blood flow to the heart; and decreased state of inflammation.

Fortunately, not all hormones are created equal. Because we use low-dose (physiologic amounts) of hormones, and because we use natural (non-synthetic) hormones, the potential for side effects is much lower than with standard, high-dose, synthetic hormones. One theoretical concern is the possibility of causing *preexisting* prostate cancer cells to grow. For this reason, a digital rectal exam and prostate specific antigen (PSA) blood test will be done before starting testosterone, and I agree to have this repeated each year thereafter. If there is any question about possible prostate cancer, I agree to have a consultation with a urologist.

A second potential concern with testosterone therapy is that it might increase one's hemoglobin and hematocrit, or thicken one's blood. This can be easily reversed by donating blood. This problem can be diagnosed with a simple blood test. Thus, a complete blood count (CBC) will be done at least annually.

A final potential concern, especially in younger men planning to have children, is that testosterone therapy may lead to a reduction in sperm count. However, this is usually a

*reversible* process, and once the testosterone is discontinued, the sperm count gradually returns to normal. In younger men taking testosterone therapy, we may encourage them to produce semen samples and have them frozen, just in case there is any permanent long-term effect in their situation. We encourage all men who are concerned about their fertility, to have a semen analysis before starting testosterone therapy.

Rarely, a patient will develop a local zone of redness (3-8 cm), tenderness, and itching at the site of pellet insertion. This is not an infection but rather temporary inflammation, and can be sign of low cortisol level due to adrenal gland insufficiency.

In the past, male athletes have abused testosterone. When they took huge quantities of synthetic testosterone, some incurred heart problems and elevated cholesterol. However, low-dose, non-synthetic testosterone has not been associated with this.

Possible complications of non-treatment may include a worsening of your symptoms.

Depending on the individual, it can take up to 90 days before symptoms will begin to improve. If you experience a problem, or if you have any questions, please contact Dr. Thomas.

I understand that Dr. Thomas is not a substitute for my primary-care physician and the care that he or she provides.

By signing below, I acknowledge I have reviewed the above information, and have been informed of the benefits and potential risks of treatment, alternative treatment options, and the risks of not treating my symptoms. I also acknowledge I have been given ample opportunity to ask Dr. Thomas questions that have been answered to my satisfaction. I hereby consent to treatment.

---

Patient's Signature

---

Doctor's Signature