

INFORMED CONSENT FOR HORMONE PELLETT INSERTION (MALE)

Patient Name: _____ Today's Date: _____

This form is designed to document that you understand the information regarding hormone restoration therapy using pellets, including the potential risks and benefits of treating and not treating your symptoms. Information is presented so that you can make an informed decision regarding your condition and your options.

Although this therapy has been approved for human use, has been around since 1935, and is popular in Europe and Australia, I understand there are currently few doctors in the United States who administer testosterone by pellets.

I have been told I am to have testosterone pellets inserted under my skin to achieve a steady delivery of testosterone hormone into my bloodstream. I understand that the benefits of testosterone may include: a) Increased energy levels and sense of well-being, b) Behavioral changes including decreased depression, anxiety and irritability, c) Improvement in cognitive function so one is less often operating "in a fog", improved short-term memory, and greater ability to stay focused to complete a task, d) Physical effects such as decreased body fat, increased muscle mass, and increased bone density, and e) Sexual benefits such as increased libido, increasing early morning erections, and increased firmness and duration of erections. I also understand that testosterone may decrease the frequency and severity of headaches. To maintain the benefits, the procedure needs to be performed 3 times per year the first year, and 2 times per year thereafter.

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

Other hormone delivery systems are available including pills, injections, creams, gels, and patches. It is Dr. Thomas's professional opinion that pellets are far superior because they provide a more natural and physiologic way to deliver hormones, and they permit more consistent and balanced levels of hormones utilizing lower dosages.

I understand there are potential concerns with testosterone therapy. One potential concern is the possibility of causing an *existing* prostate cancer to grow. For this reason, a Digital Rectal Exam and Prostate Specific Antigen (PSA) blood test is to 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 through donating blood. This problem can be diagnosed with a simple blood test. Thus, a complete blood count (CBC) should be done at least annually.

A final potential concern, especially in younger men, is that testosterone administration might decrease the development of sperm, and the sperm count may be reduced while a person is on testosterone therapy. However, to date, this appears to be a *reversible* process, and once the testosterone is discontinued, the sperm count is restored. 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 in the future to have a semen analysis prior to initiation of testosterone therapy.

In the past, male athletes have abused testosterone. When they took huge quantities of *synthetic* testosterone, some incurred heart problems and elevated cholesterol. However, the low-dose, more *natural* testosterone that is used in hormone pellets has *not* been associated with these problems.

Potential *temporary* side effects from the pellet insertion procedure can include pain, bruising, fluid retention, facial pimples, extrusion (pellets coming out), and infection. Fortunately, these side effects are not common and are easily remedied if they do occur.

Depending on the individual, it can take as little as 48-72 hours and up to 90 days before symptoms will begin to improve. You will be given written instructions on what to do after pellet insertion. If you experience a problem, or if you have any questions, please call our office.

I understand that Dr. Thomas is not a substitute for my primary care physician and the routine care that he or she should provide. I agree to hold harmless the facility (Complete Wellness Medical Center of Sanford, Inc.) and its owner (Dr. Yandell).

By signing below, I acknowledge I have reviewed the above information as well as the Notice of Privacy Practices, and have been informed of the benefits and 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 the procedure.

Patient Signature (*Do not sign until you see Dr. Thomas*)

Witness Signature