## Male Testosterone Hormone Consent Form

<u>General:</u> Bio-identical hormone pellets are comprised of naturally derived concentrated hormones. These hormones are designed to be biologically identical to the hormones a man makes in his own body but to a lesser degree with age. Bio-identical hormones have the same effects on the body as one's own hormones.

## **Benefits and Risks:**

Advantages of testosterone therapy for men include:

- a) decreasing depression, decreasing anxiety and irritability, increasing energy and motivation, stabilizing moods, allowing one to cope better, improving one's self-image and self-worth, and enhancing one's stamina;
- b) improvement in one's cognitive function so one is no longer operating "in a fog", improving short-term memory and allowing one to stay focused to complete a task;
- c) physical effects such as decreasing total body fat, increasing lean body mass, increasing muscle mass, and increasing bone mass; and,
- d) sexual benefits such as increasing libido, increasing early morning erections, possibly increasing firmness and duration of erections (Viagra or Cialis may be used concomitantly).

The above benefits do come with some risks. Very high dose use of *synthetic* testosterone has been associated with serious risks, complications and side effects including liver and heart problems as well as increases in cholesterol. **However, low-dose, non-oral, natural testosterone that is used in pellet therapy has not been associated with these problems**.

There is some risk, even with natural testosterone therapy, of enhancing an *existing* current prostate cancer to grow more rapidly. For this reason, a rectal exam and prostate specific antigen (PSA) blood test is to be completed before starting testosterone and every 12 months thereafter.

If there are any questions about possible cancer, an ultrasound of the prostate gland may be required as well as a referral to a qualified specialist. You may be asked to sign a PSA and/or rectal exam waiver if you fail to have these yearly.

While urinary symptoms typically improve with testosterone, there is the possibility that symptoms may worsen before improving.

Testosterone therapy may thicken one's blood by increasing the concentration of red blood cells. Symptoms may include headaches and dizziness. It may be associated with an elevation in blood pressure. This condition is called *secondary polycythemia*. Thus, a complete blood count (CBC) or hematocrit (HCT) should be done annually. This condition can be completely reversed by lowering subsequent testosterone doses and/or with therapeutic blood draws.

Testosterone replacement can suppress the development of sperm and the sperm count. This is especially concerning for young men. However, to date, in a majority of men, this appears to be a reversible process once testosterone is discontinued. Any men who are concerned about their future fertility should have a semen analysis prior to initiation of testosterone therapy. Currently, testosterone is not to be used as a form of male contraception.

There is the possibility that semen production will decrease while on hormone therapy. If this becomes a concern, the testosterone dose can be decreased or treatment can be discontinued. Once treatment is discontinued, semen production should return to normal.

Additionally, it is not unusual for testicular size to decrease while on testosterone therapy. This condition can be reversed with discontinuation of therapy.

2032 Lowe Street, Ste. 103, Fort Collins, CO 80525 1615 Foxtrail Drive, Ste. 190, Loveland, CO 80538

(970)223-0193 (970)223-0193 Fax: (970)223-2860 Fax: (970)669-5348 www.alluraclinic.com www.alluraclinic.com

## **Pellet Insertion:**

Sterile surgical placement of Testosterone pellets for under the skin is performed by a designated medical professional (Physician or Physician Assistant). Insertion of pellets requires the use of local anesthesia consisting of 1% lidocaine and epinephrine. A brief burning sensation is common when the anesthesia is injected. Epinephrine can cause temporary shakiness, jitteriness, and heart racing.

## **Insertion Risks**:

As with any form of implant, there is always the risk of infection, bruising, or bleeding at the insertion site. We have found that men who return to a vigorous exercise program 2-5 days after insertion have a higher risk of pellet extrusion or working themselves out of the skin. We have also found that infection at the insertion site and/or pellet extrusion can occur when the insertion site is continually rubbed or irritated by the pant waistline or belt. Instructions on the post-pellet insertion sheet must be followed to avoid such risks.

Labs and Appointments: I understand that lab work is required prior to my first appointment and if not available, then the appointment will be postponed. I also understand that labs are necessary for management of my hormone replacement, especially during the initial 6-8 months of therapy. Labs are required prior to the initial insertion, 4 weeks after the initial insertion, 2 weeks prior to each maintenance insertion. Once my hormone levels are stable, labs will be drawn on a yearly basis. Additional labs may be drawn when deemed necessary by the treating provider or when requested by you, the patient. I understand that I am responsible for any lab charges that may not be covered by my insurance company.

<u>Charges:</u> I understand that fees include the provider fee, insertion fee and testosterone pellet fee. The pellet fee varies and depends on the number of pellets I may receive. The precise amount is to be determined by the treating medical provider.

<u>Payments</u>: I understand payment is due in full at the time of services. I understand that the clinic does not accept insurance or Medicare.

I have read and understand the above. I have been encouraged and have had the opportunity to ask any questions regarding pellet therapy. All of my questions have been answered to my satisfaction. I further acknowledge that the risks and benefits of this treatment have been explained to me and I have been informed that I may experience complications, including one or more of those listed above. I accept these risks and benefits and I consent to the insertion of hormone pellets under my skin. I understand that no guarantee or assurance has been made as to the results of the procedure and that it may not cure any condition that I may have.

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Patient PRINTED Name:		
Patient Signature:		
Date of Birth:	Date:	
Provider Signature:	Date:	