



**Patient Name:**

**Date of Birth:**

## **Consent for Testosterone Replacement Therapy**

You requested evaluation for testosterone replacement. If your history and evaluation, including lab studies, are suggestive of low testosterone levels which may be satisfactorily supplemented to improvement in your symptoms, then we will proceed with treatment. Good medical practice requires us to inform you of the medical basis for administering testosterone, the risks and the benefits of testosterone hormone replacement therapy (T-HRT).

### **Medical Basis of T-HRT**

Testosterone is a hormone produced in males and females, although males generally have a much higher level. In males, testosterone is responsible for production of sperm but also many physical and personality characteristics thought of as “typically male.” For example, lean muscle mass and some aspects of body shape (including the size of the Adam’s Apple are related to testosterone. Testosterone is also largely responsible for hirsutism, which refers to body and facial hair. More important to most males is the association between testosterone and libido (sex drive), stamina, and certain aspects of physical aggressiveness (such as standing and fighting to protect people important to him).

Testosterone production begins to diminish in the third decade of life, and with it goes many of the male characteristics. Since the testes no longer produce testosterone, they may begin to atrophy, leading to a condition called hypogonadism (literally, hypo=low and gonads = testes; reduction in testicular size).

Hypogonadism is defined as testosterone deficiency with associated symptoms or signs, deficiency of spermatozoa production, or both. It may result from a disorder of the testes (primary hypogonadism) or of the hypothalamic-pituitary axis (secondary hypogonadism). Both may be congenital or acquired as the result of aging, disease, drugs, or other factors. Additionally, a number of congenital enzyme deficiencies cause varying degrees of target organ androgen resistance. Diagnosis is confirmed by hormone levels. Treatment varies with etiology but typically includes gonadotropin-releasing hormone, gonadotropin, or testosterone replacement.

### **Potential Benefits of Testosterone Hormone Replacement Therapy**

Not all men are alike so not all men should expect the same effects from T-HRT. Typical benefits to you may include:

1. Increase in energy levels and stamina
2. Increase in sex drive
3. Improvement of erectile dysfunction
4. Reduction of anxiety or agitation
5. Reduction of insomnia or sleep disturbances
6. Improvement of mood
7. Improvement of mental acuity and focus
8. Improved cardiovascular (heart) function
9. Improved pulmonary (lung) function

Low testosterone is associated with cardiovascular disease, diabetes, osteoporosis, and depression. T-HRT may prevent or reverse these conditions.



**Risks of Testosterone Replacement:**

If you choose testosterone replacement, you need to be aware of certain risks. A “risk” means it may or may not happen to you, but you need to consider this when making a decision to start or continue therapy:

1. One significant risk of T-HRT is that the testes will become more dysfunctional. This could happen if the levels of circulating testosterone become so high that a signal is sent to the brain to “turn off” all testicular production of testosterone. We limit this risk several ways:
  - a. We measure the testosterone levels before starting and during treatment. If the level is already high, we won’t give you more testosterone.
  - b. We monitor testosterone at intervals of three, six and 12 months while on H-HRT.
  - c. We give you a testosterone stimulator concurrently with Testosterone therapy. Several compounds will accomplish this, but we choose to use twice weekly capsules of enclomiphene and DIM. The dose is 25 mg of enclomiphene and 200 mg of DIM.
2. While there are several forms of testosterone available, we prefer to use the injectable form to limit certain adverse effects, including transference.
  - a. One form of testosterone that is commonly available is oral. Unfortunately, studies have determined that the hormone is nearly completely destroyed before it can circulate, so this is virtually worthless.
  - b. Another form is a gel that is applied to the body very much like an underarm deodorant. This has a very high risk of transference, so that anyone who touches this part of your skin will get the dose of testosterone. This could be a wife or other partner during sleep, or a child during a hug. This risk is so high, the unintended consequences so bad, the US FDA now requires this form of testosterone to have a special “Black Box Warning” to explain the risk.
3. We regard the safest and most effective means of testosterone replacement to be injections into a muscle, such as the gluteus, thigh, or upper arm. Injections always have some potential risks, including:
  - a. Injection site pain, bruising, swelling, bleeding and irritation. This usually resolves very quickly. It is possible to inadvertently inject into a blood vessel, which may cause discomfort for a couple of days.

<b>Potential Risks</b>	<p><b>BLACK BOX WARNING:</b> “Secondary Exposure – Virilization has been reported in children who were secondarily exposed to testosterone <u>transdermal gel</u> or solution.” Children must avoid contact with unwashed or unclothed application sites.</p> <p><b>Potential Treatment Complications:</b> Acne, Alopecia (a form of hair loss), Gynecomastia (male breast tenderness), Hypogonadism, Increased LFT, Injection site pain and redness, Oligospermia (infertility), Erythrocytosis. If any of these occur, please contact the doctor immediately.</p>
<b>Potential Benefits</b>	<p>Low testosterone is linked to CV disease, Type II diabetes, Osteoporosis, and Depression, in addition to loss of libido, erectile dysfunction, loss of muscle mass and fatigue. Testosterone replacement is expected to reduce the risk of these conditions.</p>



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**Consent for Treatment:**

I, \_\_\_\_\_, have reviewed this consent and the proposed treatment plan with Dr. Selvey and understand the options available to me, which includes no treatment, and the treatment plan proposed by Dr. Selvey. I believe the potential benefits of treatment are greater than the potential risks, and consent to initiation of treatment.

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Signature of Patient

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Date