

Balanced Life and Health

PATIENT EDUCATION AND CONSENT FOR HORMONE REPLACEMENT THERAPY

My provider, **Philip Roberts, M.D.** has explained to me that the potential benefits and risk of Hormone Replacement Therapy as are explained below:

Expected Benefits of Hormone Replacement Therapy

- Expected benefits include control of symptoms associated with declining hormone levels.
- Possible benefits of this therapy may help prevent, reduce or control physical diseases and dysfunction associated with declining hormone levels, through hormonal replacement.
- I have been fully informed, and I am satisfied with my understanding, that this treatment may be viewed by the medical community as new, controversial, and unnecessary by the Food and Drug Administration.
- I understand that my healthcare provider cannot guarantee any health benefits or that there will be no harm from the use of hormone replacement therapy.

Risks and Side Effects of Hormone Replacement Therapy

Some of the following risks/adverse reactions are derived from the official Food and Drug Administration "FDA" labeling requirements for these drugs, for therapeutic drug levels in the blood stream. My healthcare provider may prescribe these medications at dosages designed to achieve physiologic levels of hormones in my blood stream or urine generally associated with those of a 20-35 year-old person and would be within the "normal" or "average" blood concentrations of that age group.

- **General**
 - I understand that the general risks of this proposed therapy may include, but are not limited to, bruising, soreness or pain, and possible infection for hormones administered by injection.
 - I understand that there are risks (both known and unknown) to any medical procedure, treatment and therapy, and that it is not possible to guarantee or give assurance of a successful result. I acknowledge and accept these known and unknown general risks.
 - **Any medications that are compounded to include oral, topical or pellets are not FDA approved.**

THE FOLLOWING IS A LIST OF HORMONES THAT MAY BE USED IN HORMONE REPLACEMENT THERAPY:

- ☐ **Testosterone** A prescription hormone, given by injection, transdermal cream or patch. Risk and Side effects of testosterone replacement may include, but are not limited to: an increase in the red blood cells, determined by periodic measuring of your blood and increased circulation and estrogen levels. It is not a common occurrence and generally poses no health risk; it can be corrected by donating blood or with a therapeutic phlebotomy. Testosterone replacement may reduce insulin requirements in insulin-dependent diabetics. The concurrent use of testosterone with corticosteroids may enhance edema (fluid retention) formation. Edema may be a complication with testosterone replacement in patients with pre-existing cardiac, renal, or hepatic disease.

The most common immediate side effects (occurring in approximately no more than 6% of users) include, but are not limited to: acne, application site reaction, headache, hypertension (high blood pressure) and abnormal liver function test. Other side effects may include greasy hair and skin, a strong body odor, and aggressiveness.

- ❑ **Estrogen** A prescription hormone, given by injection, orally or by transdermal cream, patch or hormone pellet. Risks associated with estrogen replacement include, but are not limited to: heart attacks, blood clot formation, gallstones, increased risk of uterine cancer (for those women who have a uterus) (if progesterone is not administered with concurrently) and fibroid tumors. The Women's Health Initiative study demonstrated increased risk when estrogen replacement is initiated 10 or more years after menopause.

Estrogen replacement is not recommended in women with a history of the following conditions: breast or uterine cancer, phlebitis and blood clots, gall bladder disease, uterine fibroma, and liver disease. Side effects may include, but are not limited to: increased body fat, fluid retention, uterine bleeding, depression, headaches, impaired glucose tolerance, and aggravation of migraines.

- ❑ **Progesterone** A prescription hormone, given orally or by transdermal cream. Risks of progesterone replacement include, but are not limited to: Progestins are not the same as natural progesterone. Progestins may cancel the protective effect of estradiol, and promote constriction of the coronary arteries to a significant degree. Natural progesterone, on the other hand, may protect the endometrium, preserve the beneficial effects of estrogen on the cardiovascular system and exert no negative effects on the blood vessels that supply your heart. Progestins may cause birth defects, damage to nerve cells, blood clots, and breast cancer.

Side effects of progesterone replacement may include, but are not limited to: nipple or breast tenderness, drowsiness, fluid retention, slight dizziness, anxiety, difficulty sleeping, depression, acne, rashes, hot flashes, appetite increases and weight gain.

- ❑ **Thyroid Hormone** A prescription hormone taken by mouth. Risks/adverse reactions include, but are not limited to: palpitations and rapid heart rate, heart arrhythmias, excitability, increased metabolism. Cardiac sensitivity is a contraindication to thyroid replacement therapy. Excess amounts may increase the risk for osteoporosis in some people and suppress the body's own ability to manufacture its own thyroid hormone.

Side effects may include, but are not limited to: sleep disturbances, fine trembling of fingers, excessive hunger and thirst, sweating, anxiety, and headaches.

- ❑ **Dehydroepiandrosterone (DHEA)** DHEA is classified as a dietary supplement, given by mouth or by transdermal cream. Risks of DHEA replacement include, but are not limited to: worsening of certain cancers and should be avoided in women with breast cancer. DHEA replacement is not generally recommended in adults under age 35.

Side effects of DHEA replacement are generally dose related and may include, but are not limited to: acne or oily skin, hair growth on the face, arms or legs, acne in women, decreased HDL cholesterol, fatigue, mood changes, weight gain, and insomnia.

- ❑ **Melatonin** A non-prescription hormone given by mouth. Risks of Melatonin replacement include, but are not limited to: nighttime exacerbation of asthma. It should be used cautiously when treating some autoimmune diseases and leukemia, Hodgkin's disease or lymphoma.

Side effects of Melatonin replacement may include, but are not limited to: sleep disorders, bizarre dreams, headache, fatigue, stomach discomfort, and suppression of male sex drive.

Alternatives to Hormone Replacement Therapy

I understand the reasonable alternatives to hormone replacement therapy, which include:

- ☐ Leaving the hormone levels as they are and doing nothing. Risks may include, but are not limited to: experiencing symptoms of hormone deficiency, and increased risk for aging-related diseases or dysfunction resulting from declining hormone levels. This alternative may result in the need to treat diseases or dysfunction associated with declining hormone levels as they appear clinically.
- ☐ Treating the symptoms of declining hormone levels as they develop with non-hormonal therapies. Risks may include, but are not limited to: increased risk for aging-related diseases resulting from declining hormone levels

My Compliance Obligation While Receiving Hormone Replacement Therapy

- ☐ I agree to comply with the proposed treatment and therapy as prescribed, including the fact that I may be responsible for injecting, taking by mouth, applying to my skin, or administering the hormone(s) that may be prescribed to me, and consent to periodic monitoring, when requested, which may include:
 - Laboratory monitoring of blood or urine chemistries and hormone levels
 - Physical examinations
 - Regular screening evaluations –including annual mammograms.
 - I agree to notify you regarding all signs or symptoms of possible reactions to my therapy.
 - I agree to comply with all other healthy lifestyle activities that have been individually recommended for me. I have completely disclosed my medical history, including prescription and non-prescription medications that I am currently taking or plan to take during my treatment, as well as any other over-the-counter medications, recreational drugs or social substances, herbs, extracts, and other dietary supplements to you.
 - I agree to comply with the recommendations regarding the continuation or discontinuation of these preparations.
 - In the future I will receive recommendations in advance from you before stopping any prescribed therapeutic regimens or taking additional preparations that are not recommended by you.

I certify that I am under the care of a physician(s) for any and all other medical conditions.

By signing this document, I acknowledge that my medical condition has been evaluated and explained by my physician, who has recommended treatment and testing as stated above, and that the doctor has explained to me the potential benefits of such treatment and the risk associated with it, as well as the probable risks of not following the recommended treatment, which I fully understand.

(Date)

(Signature of patient or authorized individual)

(Relationship of authorized individual)