



Jorge Peláez, M.D.
Florida Health & Wellness Institute
1004 Scenic Highway . Pensacola, FL 32503
850.436.4444 office . 850.433.8838 fax

CONSENT FOR HORMONE REPLACEMENT THERAPY

I, the undersigned, authorize and give my Informed Consent to Jorge Peláez, M.D. for the administration of hormone replacement therapy.

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 health care 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 and for therapeutic drug levels in the blood stream. My health care 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.

Testosterone:

- A prescription hormone, given by injection, transdermal cream or patch.
- Risks of testosterone replacement include, but are not limited to: stimulation of benign and malignant prostate tumors. Testosterone replacement is contraindicated in patients with known prostate cancer.
- Side effects of testosterone replacement may include, but are not limited to: an increase in red blood cell counts, determined by periodic measuring in blood testing. It is not a common occurrence and generally poses no health risk. It can be corrected by donating blood or with a therapeutic phlebotomy. Male pattern baldness, gynecomastia (breast enlargement), diminished sperm production, and a reduction in the size of testicles may develop in men. Testosterone replacement may reduce insulin requirements in insulin-dependent diabetics. Older male patients may be at a slightly higher risk for the development of prostate enlargement when replacing testosterone. 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. It is not known whether testosterone replacement therapy will increase the risk of prostate cancer.
- 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), abnormal liver function tests, and non-cancerous prostate disorder. 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 or patch.
- Risks associated with estrogen replacement therapy include, but are not limited to: heart attacks, blood clot formation, gallstones, increased risk of uterine cancer (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.
- Synthetic 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/or liver disease. It is the responsibility of the patient to inform the prescribing physician of any and all illnesses or conditions which may fall into the above-mentioned exceptions. The prescribing physician cannot be held liable should any complication arise as the result of undisclosed historic and current medical conditions while being treated with estrogen replacement.
- 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 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 men with existing prostate cancer and 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, and prostate enlargement and male pattern baldness in men. Also, decreased HDL cholesterol, fatigue, mood changes, weight gain and insomnia.

Melatonin:

- A non-prescription hormone given by mouth.
- Risks of melatonin 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.

Oxytocin:

- A non-prescription hormone given as a triturate, which is to be dissolved under the tongue.
- Risks of oxytocin replacement include, but are not limited to: water retention and weight gain, decrease in cortisol production, increase in cerebral spinal fluid production, and low blood pressure. Oxytocin receptor activation inhibits the

growth of cells from neural, breast epithelium, endometrium, and bone tissues. Oxytocin should not be used in patients taking nitroglycerin for heart disease or with a brain stem tumor.

- Side effects of oxytocin replacement may include, but are not limited to: headache, weight gain and fatigue.

Pregnenolone:

- A non-prescription hormone given by mouth.
- Risks with pregnenolone replacement include, but are not limited to: exacerbation of various cancers and should be avoided in those with cancer of the prostate, breast or uterus. Very high doses may cause cardiac arrhythmias.
- Side effects of pregnenolone include, but are not limited to: headaches, bloating, menstrual irregularities, heartburn, acne, agitation, sedation, rash and flushing.

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 of 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 administrating 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
- 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.

Research and Economic Interests:

I understand that the prescribing practitioner is not engaged in any personal research and has no economic interests unrelated to my immediate care or treatment that may affect the physician’s choice of treatment or medical judgment.

I certify that I have been given the opportunity to ask any and all questions I have concerning the proposed treatment, and I received all requested information and all questions were answered. I fully understand that I have the right to not consent to hormone replacement therapy. I believe I have adequate knowledge upon which to base an informed consent.

I do now attest to reading and fully understanding this form and the contents and clinical meanings of such, and having discussed these procedures with my health care provider, and consent to this treatment. I hereby affix my signature to this authorization for this proposed long-term treatment. I have been given a copy of this consent form, and I understand fully any and all of the possibly represented implications and meanings of its writing and expectations.

Patient (Print Name): _____

Patient Signature: _____ Date: _____

Physician Signature: _____ Date: _____