



CONSENT FOR BIO-IDENTICAL HORMONE REPLACEMENT THERAPY

Background:

You have been diagnosed with or have an increased risk of having a hormone deficiency (ies) and your Provider has recommended treatment with bio-identical hormone replacement therapy (HRT). Some of the bio-identical hormone preparations that may be prescribed for you are regulated by pharmacy compounding laws, which follow the Pharmacy Compounding Accreditation Board (PCAB) guidelines. The use of this therapy as it relates to your diagnosis, while common in alternative practices, may be debated in the traditional medical community.

You have the right, as a patient, to be informed about your condition and the recommended conventional, integrative, complementary, alternative, non-conventional or non-standard procedures to be used so you make an informed decision whether or not to undergo the procedures after knowing the risks involved. This disclosure is not meant to scare or alarm you, but to simply inform you so you have the information needed to give or withhold your consent to the procedure or treatment.

NOTICE: Refusal to consent to the innovative, integrative, complementary or non-standard procedure shall not affect your right to future care or treatment.

Therapeutic Basis:

Many individuals have inadequate hormone levels despite technically normal blood tests. Some individuals suffering symptoms related to menopause or andropause or inability to lose weight may also benefit from these therapies. Bio-identical HRT can be used to augment hormone levels in a number of conditions where diminished hormone levels are evident.

- Estrogen therapy can maintain vaginal and urethral function and slow the progression of osteoporosis. It may also improve sleep, decrease hot flashes and night sweats, decrease pain and perhaps cognitive function, and improve libido and overall well-being. This therapy may contain one or any combinations of the following medications: estriol, estradiol, and/or estrone.
- Progesterone hormone replacement therapy can offer protection from endometrial cancers, treatment of irregular menstruation, and other low progesterone conditions. It also can improve sleep quality and decrease anxiety. For males, low dose progesterone therapy in conjunction with testosterone therapy can maximize the hormone ratios, reducing unwanted side effects.
- Testosterone replacement therapy is used to treat symptoms or lab tests suggesting suboptimal hormone levels as determined by your Provider. Low testosterone is associated with elevated cholesterols, high blood pressure, diabetes, and prostate problems. Other low testosterone symptoms include excessive fatigue, abdominal weight gain, irritability and decreased sexual drive and function.

Objectives:

Bio-identical HRT is implemented to optimize hormone levels in the blood, helping to reduce symptoms associated with low levels of these hormones.

Potential Risks:

Safety of any of these hormones during pregnancy cannot be guaranteed. Notify your Provider if you are pregnant, suspect that you are pregnant, or are planning to become pregnant during this therapy.

□ **Estrogen Therapy:** Bio-identical estrogens are available in various forms including oral capsules, troches, patches, pellets and topical creams. Adverse reactions may include bloating, breakthrough bleeding, breast swelling and tenderness, fluid retention, weight gain, liver cysts, death (e.g.-from blood clots or cancer) and mood swings. High potency conjugated estrogens (e.g. Premarin) have been associated with an increased risk of breast cancer and blood clots (the latter especially in smokers). Estriol may carry a lower risk of breast cancer and may even protect against breast cancer. Nonetheless, the whole area of estrogen replacement is undergoing further evaluation. Do not take estrogen if you have breast cancer.

□ **Progesterone Therapy:** Bio-identical progesterone is available in various forms including oral capsules, troches, vaginal or rectal suppositories, and topical creams or gels. Progesterone therapy may be sedating, so it is recommended to coordinate dosing with sleep cycle. Adverse reactions may include bloating, breakthrough bleeding, missed menstrual cycles, breast swelling and tenderness, fluid retention, weight gain, sedation, and depression.

□ **Testosterone Therapy:** Bio-identical testosterone therapy is available in various forms including sublingual drops, troches, topical creams, pellets and injection. Side effects include acne, chronic priapism (persistent, abnormal erection of the penis), change in libido, angina or heart attacks, hirsutism (facial hair growth) and scalp hair loss, clitoral engorgement, voice changes, or water retention. Because it may improve insulin resistance in males, diabetics who use insulin should monitor glucose levels closely, as less insulin may be needed. Check with your physician before adjusting your dose of insulin. If using a formulation of testosterone that is applied to the skin, a local irritation may occur.

Although the use of bio-identical hormone replacement therapy has been shown in many studies to be safer than synthetic hormone replacement therapy, the risk of cancer-related side effects is still possible. In fact, there are physicians who do not agree with the use of bio-identical hormones.

Statement of Patient:

I understand that along with the benefits of any medical treatment or therapies, there are both risks and potential complications to treatment, as well as not being treated. Those risks and potential complications have been explained to me. I have not been promised or guaranteed any specific benefit from the administration of these therapies and no warranty or guarantee has been made regarding the results of treatment. I agree to proceed with treatment and to comply with recommended dosages.

I agree to comply with requests for ongoing testing to assure proper monitoring of my treatments that may include laboratory evaluation of all aforementioned hormone levels or other diagnostic testing by a LTHC Provider, my primary care physician, or other specialist. I agree to see my primary care physician, gynecologist, or other practitioner for regular monitoring and for preventative measures that may include but are not limited to complete physicals, rectal examinations and/or colonoscopy, EKG, mammograms, pelvic/breast exams, pap smears, prostate exams, PSA levels, etc. at least on a yearly basis.

I agree to immediately report to my Provider any adverse reaction or problem that might be related to my therapy. Risks and potential complications have been explained to me and I agree that I have received information regarding those risks, potential complications and benefits, and the nature of bio-identical and other hormone treatments, and have had all my questions answered. Furthermore, I have not been promised or guaranteed any specific benefit from the administration of bio-identical hormone therapy.

I certify this form has been fully explained to me, that I have read it or have had it read to me and that I understand its contents. I agree not to undergo any treatments unless I fully understand the treatment and have discussed possible risks and benefits.

I agree to the therapy described above. I have been educated on the benefits, risks, and possible adverse reactions associated with bio-identical hormone replacement therapy.

Signature of Patient _____ Date _____

Name (PRINT) _____

Statement of Provider:

I have explained the risks and benefits of the therapy as detailed above. The patient has verbalized to me his/her understanding of those risks and benefits and gives verbal consent to initiate this therapy.

I have explained the therapy, its intended benefits and risks, and possible reactions to the patient. I have confirmed the patient has no further questions and wishes to initiate bio-identical hormone replacement therapy.

Name of PROVIDER Explaining Procedures: _____

PROVIDER Signature _____