

## Consent for Bioidentical Hormone Therapy for Women

This form is called an "Informed Consent Form." Its purpose is to inform you about Bioidentical Hormone Therapy (BHT) that your provider (physician, nurse practitioner, physician's assistant) has discussed with you. You should read this form carefully and ask any questions before you decide whether to give your consent for this therapy.

As with all treatments, there are potential risks and benefits of both treatment and forgoing treatment. Treatment carries the potential risk of unsuccessful results, complications, and injury from both known and unforeseen causes. There is no warranty or guarantee made as to a result or cure. You have the right to be informed of such risks as well as the nature of the treatment, the expected effects of therapy, the available alternative methods of treatment and their risks and benefits, and the controversies regarding the most appropriate diagnosis and treatment.

**Background:** You have been diagnosed with a relative or absolute deficiency of estrogen, testosterone, or progesterone or a combination thereof. You may potentially benefit from hormonal supplementation. Your provider has recommended treatment with BHT which consists of either progesterone and /or testosterone and/or estradiol. The goal is to provide you with the most up-to-date therapy options. You need to be sure you understand the reason that this therapy is being prescribed, the potential risks of therapy and the potential risk of declining treatment.

We also feel it is important that you know there are significant controversies regarding the best method to diagnose and treat symptoms related to perimenopause and menopause, the best methods of treatment, and the most appropriate way to monitor therapy. This is especially true when "standard" blood tests look "normal". Thus, you may consult another doctor who does not agree with the therapy. This document provides extensive information that will be summarized by your provider so that you understand the basis for the diagnosis, the treatment method, and the potential risks and benefits of treatment and declining treatment.

Do not undergo therapy until you have reviewed this document with your provider, thoroughly understand the potential risks and benefits of treatment, and have all your questions answered. The diagnosis and treatment used may be considered nonconventional, complementary or alternative. Other physicians may disagree with the need for treatment, the method of treatment and dosing, and/or the methods of monitoring. You agree to undergo testing as recommended by your provider and report any potential side effects immediately.

**Therapeutic Basis:** Many individuals have inadequate hormone levels despite technically "normal" blood tests. There are limitations to "measuring" hormone levels as it reflects what is in the serum or saliva only rather than inside the cell. Some individuals suffering symptoms related to perimenopause, menopause may benefit from these therapies. Bioidentical hormone therapy can be used to augment hormone levels in a number of conditions where diminished hormone "levels" are evident or clinically suggestive based on symptoms. The provider may prescribe these hormones at dosages designed to achieve a pharmacologic effect to reduce the symptoms of hormonal decline.

The diagnosis and treatment will involve many components including your symptoms, confounding medical issues or medications, blood levels, physical exam, response to therapy, possible side effects, individual reaction/response to therapy, and other information. Your blood levels may fall into "normal" lab reference ranges, which may not in our opinion, reflect your deficiency.

We also feel it is important that you know there are significant medical differences of opinion/controversies regarding the best method to diagnose and treat low hormone levels, whether or not blood tests are needed at all, the best methods of treatment, and the most appropriate way to monitor dosage and therapy. This is especially true when “standard” blood tests are “normal”, meaning that the result is within the normal laboratory reference range for the test. The diagnosis and treatment used may be considered non-conventional, complementary or alternative. Other physicians may disagree with the need for treatment at all, the method of treatment, dosing and/or the methods of monitoring. Thus, you may consult another doctor who does not agree with our diagnosis or therapy.

**Expected Benefits of Bioidentical Hormone Therapy may include:**

- ◆ Control of symptoms associated with declining hormone levels.
- ◆ May help prevent, reduce or control physical diseases and dysfunction associated with declining hormone levels.
- ◆ 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.
- ◆ The long-term effects of these hormones have not been established, particularly as it relates to breast cancer, and cardiovascular disease and thrombosis
- ◆ I understand that my healthcare provider cannot guarantee any health benefits or that there will be no harm from the use of hormone therapy.

**Risks and Side Effects of Bioidentical Hormone Therapy may include:**

❖ **Route of Administration**

\_\_\_\_\_ ◆ I understand that the general risks of subdermal pellet insertion and injections may include, but are not limited to bleeding, bruising, scarring, extrusion, soreness or pain, and infection. In general, pellets cannot be removed after insertion.

◆ Topical creams can be transferred to other family members and result in a local skin reaction. Benefits and Potential Risks/ Side Effects of Individual Hormones

❖ **Testosterone:**

- ◆ A prescription hormone given by subdermal pellet, injection, troche, or transdermal cream.
- ◆ It is not FDA approved for women and is considered “off-label” use for symptomatic improvement in women
- ◆ Potential benefits: increased libido, energy and sense of well- being, decreased frequency/severity of headaches, increased energy, decreased hot flashes, increase in muscle mass and decrease in visceral fat, improved insulin sensitivity, improved lipid panel, decreased risk of dementia, decreased bone loss, improved cognition and memory and help with sleep issues, reduced risk of reproductive cancers, reduced risk of cardiovascular disease.
- ◆ Risks of testosterone may include, but are not limited to: an increase in red blood cells (erythrocytosis) reduced insulin requirements in insulin-dependent diabetics, increased estradiol levels, edema (fluid retention), reproductive cancers, and cardiovascular disease.
- ◆ Side effects may include, but are not limited to: enlarged clitoris, hair loss, temporary water retention, acne, irritability, and voice changes. These are mostly dose related and usually resolve with reduction in dose. Premenopausal females MUST use birth control. Theoretically, testosterone can masculinize a female fetus.

❖ **Estrogen (estradiol and/or estriol):**

- ◆ A prescription hormone, given by subdermal pellet, oral tablet, cream, patch, or troche.
- ◆ Potential benefits: increased libido, sense of well-being, increased energy, decreased hot flashes/night sweats, decreased vaginal dryness, decreased risk of heart disease and cardiovascular disease when started in the first 10 years of menopause, decreased risk of dementia, decreased bone loss, improved cognition and memory, help with sleep issues, helps with urinary incontinence.
- ◆ Risks of estrogen include, but are not limited to: heart attacks, blood clot formation, stroke, breast cancer, liver disease, gallstones, increased risk of uterine cancer, and fibroid tumors.
- ◆ Side effects may include, but are not limited to: increased body fat, bloating, breast swelling/tenderness, fluid retention, uterine bleeding, depression, headaches, impaired glucose tolerance and aggravation of migraines.

❖ **Progesterone:**

- ◆ A prescription hormone, given orally or by transdermal cream.
- ◆ Potential benefits: protection from estrogens effect on the uterus and breast thereby reducing risk of endometrial (uterine) and breast cancer, treatment of irregular menstruation, improved sleep quality, improved anxiety.
- ◆ Side effects can include, but are not limited to: acne, drowsiness or dizziness.
- ◆ Progesterone has not been shown to cause any risks or increase the risk of thrombosis or breast cancer in the medical literature. However, long term risks of breast cancer or other medical problems have not been definitively proven.

❖ **Dehydroepiandrosterone- DHEA:**

- ◆ DHEA is classified as a dietary supplement given orally or by transdermal cream.
- ◆ Risks of DHEA include but are not limited to: worsening of certain cancers and should be avoided in women with breast cancer.
- ◆ Side effects of DHEA 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, prostate enlargement in men, male pattern baldness, decreased HDL cholesterol, fatigue, mood changes, weight gain and insomnia.

**Alternatives to Bioidentical Hormone Therapy**

\_\_\_\_\_ I understand the alternatives to bio-identical hormone therapy include, but are not limited to:

- ◆ 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 dysfunctions associated with declining hormone levels.
- ◆ Treating the symptoms of declining hormone levels as they develop with non-hormonal therapies such as SSRI's (antidepressants), sleeping pills, and herbal therapies, essential oils, lifestyle modifications such as weight loss, stress reduction, yoga, etc.
- ◆ Many of these hormones are used "off-label", which means they are not FDA approved. Many of these hormones are made by a compounding pharmacy. Off-label refers to use of, relating to or being an approved drug legally prescribed for a purpose for which it has not been specifically approved.
- ◆ Seeing another provider who believes in using non-bioidentical synthetic hormones such as Premarin and Prempro or other therapies FDA approved therapies for menopause.

**My Compliance Obligation While Receiving Bioidentical Hormone 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:

- o Laboratory monitoring of blood or urine chemistries and hormone levels
- o Physical examinations
- o 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 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.

\_\_\_\_\_ • I understand that my prescribing physician will need to see me every **4 months**, once at my annual well check and two additional follow up appointments. I will also be required to get **bloodwork about every 6 months** as ordered by my physician.

\_\_\_\_\_ • 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 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 discussing these procedures with my healthcare provider and consent to this treatment, and 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's Name: \_\_\_\_\_  
(Please Print Name)

Date: \_\_\_\_\_

Patient's Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Physician Signature: \_\_\_\_\_

Date: \_\_\_\_\_