



## **INFORMED CONSENT FOR BIO-IDENTICAL HORMONE REPLACEMENT THERAPY**

### **Background:**

Your Provider has assessed that you have, or have an increased risk of having, a hormone deficiency. 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 that you make an informed decision whether or not to undergo the procedures after knowing the risks and hazards 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 at this office.

### **Therapeutic Basis:**

Many individuals have inadequate hormone levels despite technically normal blood tests. Some individuals suffering symptoms related to menopause or hormonal imbalances 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 improve 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, PMS, and other low progesterone conditions. It also can improve sleep quality and decrease anxiety.

- 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 cholesterol, high blood pressure, diabetes, and depression. Other low testosterone symptoms include excessive fatigue, abdominal weight gain, difficulty building lean muscle mass, irritability and decreased sexual drive and function.

### **Objectives:**

Bio-identical HRT is implemented to optimize hormone levels in the body, 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, vaginal suppositories, patches 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, vaginal suppositories or topical creams. Side effects include acne, change in libido, increased risk for cardiac events (angina or heart attacks), hirsutism (facial hair growth) and scalp hair loss, clitoral engorgement in women, voice changes, or water retention. Because it may improve insulin resistance, 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, \_\_\_\_\_ (hereinafter “I”) seek the medical services of Holistic Integrative Health (“**Practice**”). I am executing this informed consent document (“**Informed Consent**”) to verify and confirm my discussion with John D. Gonzalez, DNP, APRN, ACNP-BC, ANP-C (“**Provider**”) regarding the risks, benefits, and alternatives to treatment through Practice. I am here for my own purposes and not on behalf of any third-party. I understand that I am a participant in the decision-making process and I am free to decline services or treatments at any time. I understand that I agree to bring to the attention of Practice’s clinical staff, if, at any time, I have any lack of understanding of such risks, benefits and alternatives, and inquire of clinical staff for further explanation until I have a full understanding before giving consent to any procedure or treatment.

### 1. Benefits:

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. I understand that undergoing this treatment therapy may provide benefits that include those listed above], though no particular outcome can be warranted or guaranteed.

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.

### 2. Risks:

I understand that, as with any health treatment, Bio-identical Hormone Replacement Therapy is not without risk. Potential risks of treatment include, but are not limited to, those risks specifically listed above, as well as allergic reactions, sensitivities, adverse effects from, or in response to, bio-identical hormone replacement therapies, increased risks of contracting cancer, and failure to improve or worsening of my condition. Other side effects and risks may occur.

I agree to inform Practice’s clinical staff of all known factors that might affect treatment, including, but not limited to, all medications, drugs, drug sensitivities and allergies, history of seizures, fits or fainting, presence of a pacemaker, bleeding disorder, use of anti-coagulants, damaged heart valves or occluded vessels, immune deficiencies, or other special risks of infection, as well as any other significant factors within my knowledge. I further agree to inform Practice’s clinical staff of any disorder or state of mind that might affect my capacity to make informed health decisions, and should any such impairment exist, I will provide information regarding a surrogate decision maker.

Those risks and potential complications have been explained to me, and I have had the opportunity to ask questions and I have had all my questions answered to my satisfaction. I agree to proceed with treatment and to comply with recommended dosages.

### 3. Alternatives:

As alternatives, Provider encourages me to speak with and consider the advice of other Providers, including conventional or mainstream physicians and providers. Provider will consult with, but does not replace, care currently provided to me by other physicians or providers, such as my internist, gynecologist, cardiologist, gastroenterologist, pediatrician (in the case of children), oncologist or other specialty care provider. In addition to discussing other modes of therapy that may be used for the treatment of my condition, Provider and I have discussed, and I understand, the possibility of a referral to a specialist for my condition(s) if I have not already consulted with an appropriate specialist. Provider has advised me that he/she does not admit patients to the hospital or treat hospitalized patients.

**I understand that I have the right to revoke my consent to treatment, stop treatment, or refuse treatment at any time, even after treatment has begun. I understand that my refusal to consent or revocation of consent shall not affect my right to future care or treatment at this office.**

I understand that as a condition of my treatment by Practice, I must maintain a relationship with an outside physician to act as my primary care provider and to provide emergency and urgent care. If I encounter a medical emergency and am not able to obtain care from my primary care physician(s), I will contact 911 or report to a hospital emergency department as appropriate.

### 4. Additional Statements:

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 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, DEXA bone density tests, pelvic/breast exams, pap smears, general blood test screening, 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. 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 to not being treated. Those 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.

---

**NOTE: Do not sign this form unless you have read it and feel that you understand it. Ask any questions you might have before signing this form. Do not sign this form if you have taken medications which may impair your mental abilities or if you feel rushed or under pressure.**

**By signing below, I acknowledge and certify that I have had opportunities to ask questions and have had them answered to my satisfaction; I have read, or have had it read to me, and fully understand the foregoing Informed Consent for Bio-Identical Hormone Replacement Therapy, and I have all of the knowledge I currently desire; I have discussed the issues noted above with Provider; and I agree and accept all of the terms above. I am legally competent and have sufficient knowledge to give voluntary and informed consent.**

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 that the patient has no further questions and wishes to initiate bio-identical hormone replacement therapy.

Name of PROVIDER: \_\_\_\_\_

PROVIDER Signature \_\_\_\_\_