CONSENT AND INFROMATION FOR BIO-IDENTICAL HORMONE REPLACEMENT THERAPY

**To The Patient: Background:**

You have been diagnosed with or have an increased risk of having a hormone deficiency (ies) and your doctor has recommended treatment with bio-identical hormone replacement therapy (HRT). Some of the BioIdentical hormone preparations that may be prescribed for you are regulated by the pharmacy compounding law, which is part of pharmacy compounding laws. The use of this therapy as it relates to your diagnosis, while common in alternative and weight loss 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; it is simply an effort to make you better informed so you may 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 nonstandard 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 hormone replacement therapy 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 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 side effects.

Testosterone replacement therapy is used to treat symptoms or lab tests suggesting suboptimal hormone levels as determined by your doctor. Low testosterone is associated with elevated

cholesterols, Blood Pressure, Diabetes and prostate problems. There are ongoing discussions within the medical community whether treating to optimize testosterone will increase or decrease these problems.

**Objectives:** Bio-identical hormone replacement therapy 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 physician or if you are pregnant, suspect that you have become pregnant, or if you are planning to become pregnant during this therapy.

Estrogen Therapy: Bio-identical estrogens are available in various forms including oral capsules, troches, 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), and perhaps even estradiol, 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, 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. In women, excessive testosterone or DHEA doses could increase the risk of diabetes or facial hair.

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 use bioidentical 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 Chronicity physician, 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 physician 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 Bioidentical 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) _____

If patient is a minor Parent/Legal Guardian Signature_____ Date

Name(PRINT)_____Relationship

**Statement of clinical educator:**

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-icentical hormone replacement therapy.

Name of Physician Explaining Procedures: _____

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 giving verbal consent to initiate this therapy.

Physician Signature_____ Date_____