BIO-IDENTICAL HORMONE RESTORATION & NUTRITIONAL THERAPY CONSENT FORM

Laser Solutions Med Spa

Name _____

This form is called an "Informed Consent Form." Its purpose is to inform you about bio-identical hormone restoration and nutritional therapy that your medical provider(s) has/have recommended for you. You should read this form carefully and ask any questions before you decide whether to give your consent for this therapy.

1. As with all treatments, there are potential risks and benefits of both treatment and from 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 benefits or effects of such therapy, the available alternative methods of treatment and their risks and benefits, and the controversies regarding the most appropriate diagnosis and treatment of low or suboptimal bio-identical hormone restoration and nutritional therapy.

2. The Principals of Medical Ethics adopted by the American Medical Association in 1980 states that a physician shall continue to study, apply, and advance scientific knowledge, make relevant information available to patients, colleagues, and the public. An essential component of informed consent requires that in the absence of medical certainty, patients can choose among medically indicated treatments. The American Medical Association's code of ethics states, "The principle of patient autonomy requires that competent patients have the opportunity to choose among medically indicated treatments and to refuse any unwanted treatments." Because choice can only be preserved by understanding and acknowledging divergent viewpoints on treatment options and providing those treatment options, this document, along with the discussion with your medical provider, is designed to provide you with such information.

BACKGROUND You have been diagnosed with or have an increased risk of having hormone or nutritional deficiency(ies) and your doctor has recommended treatment with bio-identical hormone replacement therapy (HRT) and nutritional supplementation. Some of the Bio-Identical hormone preparations or nutritional supplementations that may be prescribed 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 nonstandard procedures to be used so that you make an informed decision whether or not to undergo treatment or 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 this therapy. NOTICE: Refusal to consent to the integrative, complementary, alternative, non-conventional or nonstandard therapy shall not affect your right to future care or treatment. We respect our patients' point of view and strive to find medical solutions that are optimal for all our patients.

THERAPEUTIC BASIS Many individuals have inadequate hormone levels despite technically normal blood tests. Some individuals suffering symptoms related to perimenopause, menopause or andropause may also benefit from these therapies. Bio-identical hormone replacement therapy and nutritional supplementation can be used to augment hormone levels in several conditions where diminished hormone levels are evident or clinically suggestive. Your provider may prescribe these hormones or supplements at dosages designed to achieve physiologic levels of hormones in the blood stream generally associated with those of a 20-35-year-old person and would be within the "normal" or "average" blood concentration of that age group. The diagnosis will involve many components including your symptoms, confounding medical issues or medications, blood levels, physical exam 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 or controversies regarding the best method to diagnosis low hormone or vitamin levels, the best methods of treatment and the most appropriate way to monitor and decide proper 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 and other physicians may disagree with the need for treatment at all, the method

of treatment, dosing or the methods of monitoring. Thus, you may consult another doctor who does not agree with our diagnosis or therapy.

_____ (initial) Estrogen hormone restoration can maintain vaginal and urethral function and slow the progression of osteoporosis. It may also improve hot flashes and night sweats, sleep, decrease pain and perhaps cognitive function, and improve health of the blood vessels and cholesterol metabolism and overall well- being. This therapy may contain one or any combinations of the following medications: estriol and estradiol.

_____ (initial) Progesterone hormone restoration can offer protection from endometrial cancers (primary use) treatment of irregular menstruation, and other low progesterone conditions. It also can improve sleep quality and decrease anxiety.

_____ (initial) Testosterone hormone restoration is used to treat symptoms or lab tests suggesting suboptimal hormone levels as determined by your provider. Low testosterone is associated with poor glucose metabolism, insulin resistance and diabetes, weight gain, bone loss and increased fracture risk, increased risk of heart disease, decrease in mental acuity and sharpness, deceased libido and sexual function, increase in migraine headaches and symptoms of fibromyalgia including muscle and joint aches and pains. Testosterone therapy can reduce your risk of breast cancer and previously testosterone was used as part of breast cancer treatment protocols. However, prior to starting testosterone therapies in women with current breast or previous breast cancer, we will obtain your oncologist's "approval" to start this therapy.

OBJECTIVES Bio-identical hormone replacement therapy is implemented to optimize hormone levels in the blood and help to reduce symptoms associated with low levels of these hormones. You have been recommended the following restorative hormones or nutritional supplements. (checked below). Please read the potential risks sections very careful. You may be asked to read and sign a more comprehensive consent for thyroid restoration in addition to this form.

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.

_____ (initial) Estrogen Therapy: Bio-identical estrogens are available in various forms including oral capsules, troches, patches, topical creams and subcutaneous pellets. Adverse reactions may include bloating, breakthrough bleeding, breast swelling and tenderness, fluid retention, weight gain, liver cysts, growth in fibroids or endometriosis, death (e.g.-from blood clots or cancer) and mood swings. *High potency conjugated estrogens with synthetic progestin (e.g. Provera), has been associated with increased risk of breast cancer and blood clots and cardiovascular effects such as heart attack and stroke (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 and much controversy exists surrounding hormone restorations. Do not take estrogen if you have breast cancer. To mitigate the cardiovascular event risk associated with the first pass liver effect (which increases clotting factors) many recommend avoiding oral estrogen and testosterone hormone replacement with synthetic forms.

_____ (initial) 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.

_____ (initial) Testosterone Therapy: Bio-identical testosterone therapy is available in various forms including sublingual drops, troches, topical creams, injection and subcutaneous pellets. Side effects include in women include acne, change in libido, hirsutism (facial hair growth) and scalp hair loss, nipple sensitivity, clitoral engorgement, aggression, voice changes, increase in body odor or water retention. Side effects in men include chronic priapism (persistent, abnormal erection of the penis), decreased sperm count and fertility, prostate enlargement, aggression, testicular shrinkage, increase in blood pressure, increase in breast tissue (which is usually due to estrogen excess), increase in red blood cells, If using a formulation of testosterone that is applied to the skin, a local irritation may occur. In men using higher doses of testosterone blood thickening (Secondary Polycythemia Vera) can occur and if left unresolved can lead to increased risk of blood clots, heart attack and stroke. This may be corrected in some cases by donating blood or with a therapeutic phlebotomy. Long term supratherapeutic levels of testosterone can lead to liver abnormalities and worsening kidney function. *Although most of the data suggests that testosterone lowers prostate cancer in men, there are many experts that disagree with this based on the original Huggin study in 1941 which had one patient developing

prostate cancer after starting testosterone. Testosterone may cause an increase in prostate size and increase in PSA levels. Patients are required to undergo PSA blood testing and digital rectal exam (when clinically appropriate) on a routine basis as recommended by your provider. Testosterone restoration is contraindicated in patients undergoing active prostate cancer treatment or known prostate cancer (with some exceptions as agreed upon by patient and provider). Testosterone may improve insulin resistance in patients; diabetics who use insulin should monitor glucose levels closely, as less insulin may be needed. Check with your provider before adjusting your dose of insulin or other diabetes mediations.

FEMALES ONLY Patients who are not sterilized and not menopausal are advised to continue reliable birth control while participating in pellet hormonal replacement therapy. Testosterone is category X (will cause birth defects and possible virilization) and cannot be given to pregnant women. YOU MUST BE STERILIZED OR USE AN EFFECTIVE BIRTH CONTROL METHOD TO USE HORMONE PELLETS. My method of birth control is: ☐ ABSTINENCE ☐ BIRTH CONTROL PILLS ☐ HYSTERECTOMY ☐ IUD ☐ MENOPAUSE ☐ TUBAL LIGATION ☐ VASECTOMY ☐ OTHER _____

In addition, we ask that our female patient have had a normal pap smear and mammogram within one year of insertion.

____ (Initials) I have had a normal pap smear and mammogram within the past year, or I am no longer medically required to have them.

____ (Initials) I have NOT had a Pap smear or mammogram within the last year. I voluntarily choose to undergo pellet insertion today. I am aware that if any breast or uterine issues arise and/or develop while on pellet therapy, I release Dr. Russell Gornichec MD from any liability should this occur.

PATIENT FOLLOW UP AND RESPONSIBILITY As with other therapies, the response to Bio-identical hormone restoration/supplementation and nutritional supplements can vary significantly, you agree to discuss any change in your condition or therapy with your prescribing medical provider. You also agree to comply with requests for ongoing testing to assure proper monitoring of your treatments that may include laboratory evaluation of all hormone levels or other diagnostic testing. You agree to see your primary care physician, gynecologist, or other practitioner for regular monitoring and for preventative care 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. You agree to immediately report to your medical providers any adverse reaction or problem that might be related to your therapy.

SUMMARY You agree that you have been given an opportunity to ask questions about your condition, about conventional "standard" methods of diagnosis and treatment, about integrative, alternative and complementary forms of diagnosis and treatment, about the risks of treatment and the risks of nontreatment, and the risks and hazards involved, and believe that you have sufficient information to give this informed consent. 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. You certify that this form has been fully explained to you, that you have read it or have had it read to you or explained to you and that you understand its contents. You agree not to undergo any treatments unless you fully understand this agreement. You agree to call come into the office to ask any questions about the controversies, risks and benefits of treatment (and not treating) and not continue treatment until all your questions are answered or clarified. You are able to download this document to re-review before starting or continuing treatment and agree that you will read the document in its entirety before your next visit or refill and call or come into the office to answer any questions about the controversies, risks and benefits of treatment (and not treating) before continuing treatment. You also agree not to start any medications until you are comfortable with this agreement and willingness to sign this document.

_____ _____

Signature of Patient Date