CONSENT FOR BIO-IDENTICAL HORMONE RESTORATION AND NUTRITIONAL THERAPY

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 or not 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 have the opportunity to 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 peri-menopause, 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 a number of conditions where diminished hormone levels are evident or clinically suggestive. The providers at DeRosa Medical/MiraVita 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.

_____ **Thyroid hormone replacement** can help with fatigue/chronic fatigue syndrome, depression, heart disease, high cholesterol, fibromyalgia, infertility, weight gain, irritable bowel syndrome, cold intolerance, body aches, thinning hair or hair loss, dry skin, heavy periods, premenstrual syndrome, cold extremities, water retention, constipation, muscle cramps, stiff or painful joints, hoarse voice, poor immunity and diminished sweating.

_____ **Vitamin D optimization** can help reduce the risk of many illnesses, including common cancers such as breast, colon and prostate, multiple sclerosis, rheumatoid arthritis, and cardiovascular disease. In addition, it is a "great masquerader" often resulting in incorrect diagnoses such as fibromyalgia, mixed connective tissue disorders, and depression to name a few. It has anti-inflammatory properties. One of its primary roles in the body is to aid in calcium absorption and metabolism to protect our bones and reduce our risk of fractures. It also helps reduce falls risk as it helps the body stay balanced.

_____ **Vitamin B12 optimization** can help with energy, mental clarity, mood and glucose metabolism and weight. It helps reduce neuropathic pain and decrease sensation of our hands and feet and is often recommended in patients with these disorders or diabetes. It is also used in the treatment of certain blood disorders.

_____ **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.

_____ **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.

_____ **Testosterone hormone restoration** is used to treat symptoms or lab tests suggesting sub-optimal 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.

_____ **Aromatase Inhibitors (Femara) utilization**: Although the prime indication for these types of medications is in the treatment of breast cancer in women, there is increasing utilization of this medication in men. Aging men, men who are overweight, and those who are genetically predisposed can have "estrogen excess" due to converting (aromatization) too much of their testosterone to estrogen. Our fat cells contain the enzyme "aromatase" which promotes this conversion. This estrogen conversion can lower a man's testosterone levels but also cause estrogen to spike to higher levels causing negative consequences and side effects. Estrogen excess can cause gynecomastia (breast enlargement), hot flashes and night sweats, infertility, impotence, mood changes, prostate enlargement and increased risk for prostate cancer.

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. If your hormone restoration involves having subcutaneous pellets placed, you will have additional consents and forms to fill out as well.

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.

_____ **Thyroid replacement therapy** can cause rapid heartbeat, irregular heartbeat, chest pain or tightness, shortness of breath, nervousness, irritability, sleeplessness, tremors, excessive sweating, heat intolerance, weight loss, seizures, stomach cramping and diarrhea, hair loss, bone loss or changes in menstrual periods.

_____ **Vitamin D** is a fat soluble vitamin and very hard to replace. However if the levels of vitamin D become too high, most people do not experience any symptoms. However, blood monitoring is essential. However, some people will experience weakness, fatigues, sleepiness, headaches, loss of appetite, dry mouth, metallic taste and nausea and vomiting. Taking excess amount of vitamin D for long periods of time can result in unsafe levels of calcium in the blood especially if taking calcium supplement or thiazide diuretics.

_____ **Vitamin B12 optimization** can result in side effects, but these are very rare as most people will get rid of the excess B12 in their urine. It may cause mild diarrhea, heart palpitations, chest pain, and anxiety and breathing problems. Sleep may be disturbed due to the increase in energy it may provide.

_____ **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), the providers at DeRosa Medical/MiraVita do not use synthetics or oral forms of estrogen,. We also only use bio-identical versions of hormones (with rare exceptions). The data has not proven an increase breast cancer risk with these preparations, and in some studies suggest that it may reduce the risk.**

_____ **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, 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 the majority 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.

_____ **Aromatase Inhibitors (Femara) utilization:** The side effects from using an aromatase inhibitor include dizziness, muscle and joint aches and pain, joint disorders such as arthritis, cholesterol abnormalities, mood changes (such as depression or anxiety), blurred vision, nausea/vomiting lowered sex drive, bone loss with increased risk of developing osteoporosis and fatigue. You will need to be monitored with blood levels to ensure proper ratio between testosterone and estrogen as well as ensure that your estrogen levels do not become too low.

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 medical providers who do not agree with use bio-identical hormones.

_____**Patient Initials**

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 by a DeRosa Medical/MiraVita provider or other specialist. 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.

_____**Patient Initials**

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 non-treatment, 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**_____

_____

Name (PRINT)

IF PATIENT IS A MINOR PARENT/LEGAL GUARDIAN

Signature _____ **Date**_____

_____

Name (PRINT)

_____ **Relationship to Patient**

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-identical hormone restoration or nutritional supplementation therapy.

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.

NAME OF PROVIDER/EDUCATOR EXPLAINING PROCEDURES/THERAPIES

_____**Date:** _____