

Robinson Drug Shop

2 East Main Street

Mendham, NJ 07945

Phone: 973.543.2525

Fax: 973.543.2396

Consent to Treatment

The Nature of the Treatment

I hereby give my consent to evaluation and treatment of menopause, andropause, thyroid disorders, adrenal fatigue/stress and other hormone imbalances by the administration of bioidentical hormone replacement therapy and/or nutritional supplements, including vitamins, minerals and anti-oxidants and/or drugs designed to alter hormone levels. The nature of the procedure is to raise levels of hormones in my body to levels which will improve quality of life, improve my functional ability and the goal of which is to decrease the incidence of sickness and disease. Regarding the nutritional supplements, the goal is to raise levels of vitamins, minerals and anti-oxidants in order to maximize the physiologic processes in my body and minimize damage by naturally produced free radicals.

The General Nature and Extent of Treatment-Related Risks

All hormone deficiencies have unwanted symptoms and the potential for illness when the hormone level is low. In addition, all hormones have unwanted symptoms and the potential for harm when the levels are too high. Along with my doctor and pharmacist, I believe that it is when the hormones are within a range to eliminate my symptoms but not cause side effects and in addition when the hormones are balance with the other hormones of the body, that we will obtain the optimum goal in my health.

In menopause, women lose the majority of their hormones within a few years causing in many cases severe distress both mentally and physically. Through the use of bioidentical hormone replacement therapy, one can counter this decline and help alleviate the symptoms due to menopause. In addition, it is now being shown that bioidentical hormone therapy is effective in the treatment of osteoporosis, as well as other disease process associated with hormone decline as we age.

The potential adverse effects for women on estrogen, progesterone and/or testosterone include breast swelling and/or discomfort, fluid retention, dizziness, palpitations, break through bleeding requiring an endometrial biopsy, acne, unwanted hair growth, oily skin and hair, headache, increased risk of gallbladder disease, increased risk of blood clots, may worsen ovarian cyst, may worsen uterine fibroids, may worsen endometriosis, may worsen fibrocystic disease and may increase the incidence of breast and uterine cancer.

In andropause, men gradually lose their ability to produce testosterone and some men develop elevated levels of estrogen. As men undergo an ever increasing loss of testosterone, they are faced with anxiety, irritability, erectile dysfunction, bone loss, muscle loss, loss of strength, and loss of energy and memory impairment.

The possible side effects for men on testosterone replacement are acne, oily skin and hair, unwanted hair growth, enlargement of the prostate, loss of sperm production (sterility), enlargement of breast tissue, testicular atrophy (shrinking), and in some study an increased risk of prostate cancer growth.

In respect to adrenal function, my doctor/pharmacist has explained the risks of adrenal therapy with me including the long term use of corticosteroid (cortisol) which has been associated with osteoporosis, suppression of my immune system and can lead to the adrenal glands not producing

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enough hormones (adrenal suppression). I understand that my doctor will use other methods to help reestablish my own adrenal hormone production, but that this may involve the short term use of cortisol. In addition, I will be informed of long term complications if my doctor/pharmacist and I feel that long time use of cortisol is indicated.

In hypothyroidism, many studies have shown how physicians under-treat this condition. I understand that my physician will be working with me on resolving my symptoms and improving my quality of life by using my symptoms not simply my thyroid hormone levels to monitor the treatment of my disease. I understand that the potential side effects in using thyroid medication including osteoporosis, palpitations, dizziness, psychiatric problems (mania), and heart beats so fast that I could pass out or end up hospitalized.

In respect to aging and the incidence of adult growth hormone deficiency syndrome, I appreciate that there are certain risks associated with the use of human growth hormone. While growth hormone has been shown to increase muscle mass, lower fat mass and improve bone density, it has yet to be established the clinical guidelines for the diagnosis and treatment of such a hormone loss. Therefore, my doctor/pharmacist and I may discuss the benefits of human growth hormone and the associated risks. These risks include water retention, which may result in leg swelling and elevated blood pressure, and which may be reversed with dose adjustment, mild increase in fasting blood sugar and occasional bruises at the injection site. I may also develop infection at the injection site if I use improper technique.

I understand that there are reasons to avoid the use of human growth hormone, if I am prescribed such a medication, and they are: the presence of a cancer or tumor; uncontrolled diabetes; unusual lung diseases such as pulmonary fibrosis; pneumoconiosis; bronchiolitis; obliterans; Hermansky-Pudlak Syndrome; systemic sclerosis or pregnancy. I do not currently have nor have I been diagnosed with any of these medical problems. I understand that if I am diagnosed with any of these medical problems, I should stop the entire treatment protocol immediately and notify my physician, so that my treatment plan can be re-evaluated. I understand that taking growth hormone raises IGF-1 levels in the blood. In addition to the risks discussed above, I am aware that there are reports that indicate there may be an increased risk of prostate cancer associated with higher IGF-1 levels.

Safety of Hormone Replacement

Although in my physician/pharmacist's opinion, the majority of data points toward safety, no one has yet proven or has yet disprove a causal relationship between the use of bioidentical hormone therapy and cancer. I understand that careful surveillance and close monitoring are requirements of all patients to minimize any possible risk.

I understand there are other studies that point to a higher incidence of cancer in patients who take bioidentical hormone replacement therapy. However, studies like these, which show an association (two variables present simultaneously), do not demonstrate cause and effect. I realize that it may be a number of years before we know if there is any true cause and effect between bioidentical hormones and increased risk for cancer in women or men.

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I also understand there are possible benefits associated with these procedures. I understand that no guarantee has been made to me regarding outcomes neither of this treatment nor on resolution of my symptoms. I understand that not all patients receive the same degree of response. I also understand that the benefits derived from therapy will cease and those derived from hormone therapy and drugs that alter hormone levels may not reverse if the therapy is discontinued.

I also understand that if I am female and become pregnant, I should stop the entire treatment protocol immediately and notify my physician. I understand that this hormone therapy is not for the purpose of preventing pregnancy, and that if I become pregnant on this therapy it could present risk to the fetus (unborn child).

I understand that although each hormone has been approved by the FDA for use in the treatment of certain diseases. I also understand that the FDA only approves or disapproves of products made by manufacturers which are produced in an established dosage and form. Therefore by definition, the FDA does not "approve" or "disapprove" of bioidentical hormones which are given in an individual dose and in an appropriate form for each patient as determined by my doctor and my consulting pharmacist at Robinson Drug Shop. I also understand that my doctor may choose to discuss with me and provide to me medications that are off-label in order to offer to me the widest range of therapies possible. ("Off-label" use means the use of FDA approved drugs for purposes other than those for which the FDA has approved them.) "Off-label" prescribing is a legal and common practice by physicians in the United States.

I also understand that my physician may recommend the use of other drugs, which are only available outside the United States and are not approved by the FDA. I understand that these products may only be available under the FDA's personal use importation policy. (The FDA allows for the importation of small amounts of drugs that are legal in other countries under the personal use importation policy if certain requirements are fulfilled.) I will use such drugs as directed for my condition and in accordance with the FDA's policy. I understand that the use of these medications is completely elective.

Any questions I have regarding this treatment have been answered to my satisfaction. I understand that I will be responsible for administering the hormones prescribed to me. I will conform and comply with the recommended dose and methods of administration. I also agree to conform to the request for initial and subsequent blood tests, as required to monitor my hormone levels. I understand that failure on my part to follow my physician's recommendations in dosage and use of my hormones and medication may result in unwanted and potentially harmful problems. I understand that failure to have appropriate laboratory testing done at the interval established by my physician and failure to follow up with my physician/consulting pharmacist at the recommended appointments may lead also to adverse (unwanted) side effects.

I authorize my physician to perform this treatment. I understand they will be assisted by other health professionals, as necessary, and agree to their participation in my care as it relates to anti-oxidant and hormone modulation therapy. I certify that I am under the regular care of another physician for all other medical conditions. I understand that this is a specialized practice and does not hospitalize patients. I also understand that I will continue under the care of my other physician(s) for any on-

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going medical condition as well as for any medical consultation that I may need. I assume full liability for any adverse effects that may result from the non-negligent administration of the proposed treatment. I waive any claim in law or equity for redress of any grievance that I may have concerning or resulting from the procedure, except as that claim pertains to negligent administration of the procedure.

I hereby confirm that the nature and purpose of portions of the aforementioned treatment are considered by some to be medically unnecessary and/or experimental because they are not aimed at treating a disease, and there are no long-term studies documenting the results. The risks involved and the possibilities of complications have been explained to me. I fully understand that the treatment to be provided may be considered experimental and unproven by scientific testing and peer-reviewed publication.

I further consent to the utilization of the results of my progress in any research study performed by my physician. I understand that my name will not be used and that every effort will be made to protect my privacy. I also understand that photographs taken of me by my physician will not be used without my expressed written authorization. I understand that I may suspend or terminate treatment at any time and hereby agree to immediately notify the physician of any such suspension or termination.

To attest to my consent to this treatment, I hereby affix my signature to this authorization to treatment.

Patient Name (please print above)

Witness Name (please print above)

Signature of Patient (please sign above)

Signature of Witness (please sign above)