GRAMERCY PARK INTEGRATIVE
DR. DLADLA

HORMONE REPLACEMENT THERAPY CONSENT

Select one:

_____ My physician has recommended hormone replacement therapy (HRT) for me based on a deficiency of estrogen, progesterone, testosterone, DHEA, or cortisol determined by clinical symptoms/signs and laboratory analysis.

_____ My physician has recommended a trial of hormone replacement therapy for me based on a hormone deficiency determined by clinical symptoms/signs, despite normal laboratory analysis. However, some patients with laboratory analysis indicating hormone levels on the low end of normal range combined with symptoms experience symptomatic improvement with therapy.

Nature of Therapy

Hormone replacement therapy (HRT) is often prescribed to women during perimenopause (the time from first symptoms to up to several years beyond the last period) and menopause (starting one year after the last period) for symptoms of hot flashes, vaginal dryness, loss of libido, depression, irritability or PMS-like symptoms, bone loss and osteoporosis or its prevention, and cardiovascular disease.

Estrogen is only approved by the FDA for hot flashes and osteoporosis. Using estrogen for other symptoms or conditions is considered 'off-label' use. Progesterone is FDA approved only in women who have not had a hysterectomy to protect the uterus from uterine cancer (a potential side effect of estrogen therapy). Testosterone and DHEA are not currently FDA approved for use in perimenopausal or menopausal symptoms.

Synthetic, animal derived, or bio-identical hormones may be prescribed. The FDA does not support the use of bio-identical hormones and has posted the following statement regarding their use.

"The potential public health risks from compounded BHRT drugs are significant. Compounded BHRT drugs have not been demonstrated to be safe and effective. Many of these compounded BHRT drugs are labeled and advertised as having benefits that have been definitively disproved or for which there is no evidence. Furthermore, there is no scientific data to support the contention that compounded BHRT drugs carry fewer risks for women than FDA approved prescription hormone therapy drugs. Claims that are false or misleading can have significant health consequences for women."

HRT prescriptions may be obtained from conventional pharmacies or from compounding pharmacies. Compounded hormone prescriptions are not FDA approved. HRT may be administered orally, vaginally, or topically via creams or patches. Hormone creams applied topically to the skin may cause transference to others. Hormone creams and patches may result in skin irritation at the application site.

Potential Risks of Hormone Replacement Therapy

This authorization is given with the understanding that any treatment involves risks. It is not possible to anticipate all side effects. A study called the Women's Health Initiative, published in 2002, involving over 160,000 women between ages of 50 and 79, determined some significant and substantial risks of this particular treatment, which are listed below.

Cardiovascular Disease: The risk of heart attacks was increased in the group of women taking combination hormone replacement to 37 per 10,000 person-years vs. 30 per 10,000 person-years in women who did not get the combination hormone therapy. This means if 10,000 women took the medication for 1 year, 37 of 10,000 who took the combination hormone would have had a heart attack in that year, but 30 of the 10,000 who did not take the hormone would have had a heart attack.

Invasive Breast Cancer: The risk of invasive breast cancer was 38 per 10,000 person-years for women taking combination hormone therapy vs. 30 per 10,000 person-years for similar women who did not take the hormone.

Strokes: The risk of stroke was 29 per 10,000 person-years for women taking combination hormone therapy vs. 21 per 10,000 person-years for similar women who did not take the hormone.

Venous Thromboembolism (blood clots): The risk of venous thromboembolism was 34 per 10,000 person- years for women taking combination hormone therapy vs. 16 per 10,000 person years for similar women who did not take the hormone.

Medical science is always learning new information; this could include the discovery of other significant risks to me besides the ones listed above. The risks listed here represent the most common significant risks, but others may exist.

Potential Benefits Of Hormone Replacement Therapy

The potential benefits of taking combination hormone replacement therapy may include the potential relief of menopausal symptoms. Additionally, the Women's Health Initiative study found the following benefits to taking combination hormone replacement therapy:

Reduced Incidence of Hip Fractures: Women who took the combination hormone therapy had lower risks of hip fractures (10 per 10,000 person-years of women who took HRT got hip fractures, while 15 per 10,000 person-years of women who did not take HRT got hip fractures).

Reduced Incidence of Colorectal Cancer. Women who took the combination hormone therapy had lower risks of colorectal cancer (10 per 10,000 person-years of women who took HRT got colorectal cancer, while 16 per 10,000 person-years of women who did not take HRT got colorectal cancer).

Consent to Therapy

In consideration of the care and treatment to be provided to me by my physician, the undersigned consents to and agrees to the following conditions:

1. **Consent to Treatment**: I have discussed the reasons for undergoing Hormone Replacement Therapy with my doctor and understand why he/she is prescribing it. I understand and have discussed the risks and potential side effects of Hormone Replacement Therapy with my doctor or clinician. I understand and accept these risks, and I wish to proceed with Hormone Replacement Therapy. I understand that in order to continue treatment and monitor my care, regular office visits and repeat lab work may be required. I understand that I do not have to undergo this treatment and that I may decide to discontinue it at any time. I have been told how to use this medication or treatment in such a way that I fully understand. I have been informed that if any supplements have been recommended by my physician I may purchase them wherever and from whomever I prefer and that I may choose whether or not to take them. Based upon the foregoing, I voluntarily consent to Hormone Replacement Therapy to be provided by my physician and its associated physicians, clinicians, and other personnel. I agree that I will follow all recommendations concerning the use of testosterone, including, but not necessarily limited to, lab tests and appointments at regular intervals. I agree to take Hormone Replacement Therapy as directed.

   The difference between synthetic hormones and bio-identical hormones has been fully explained to my satisfaction. I understand that there has been greater research done on synthetic hormones. I understand that while the risks of bioidentical hormones may not be the same as the risks with synthetic hormones in some cases, more research is needed to fully understand the risks associated with use of bio-identical hormones. I understand that bio identical hormones and compounded hormone preparations are not FDA approved.

2. **Results not guaranteed.** I am aware that the practice of medicine and other health care professions is not an exact science and I further understand and acknowledge that no guarantee has been or can be made as to the results of the treatments or examinations by my physician, including, but not limited to, the results of Hormone Replacement Therapy.

3. **Use and Disclosure of Protected Health Information**: I consent to the use and disclosure of my/the patient's protected health information for purposes of obtaining payment for services rendered to me/the patient, for treatment, and for health care operations.

4. **Prior Authorization**: I understand that many insurance companies or other payers require pre-authorization or referrals for certain treatment, tests and /or procedures. I understand that it is my/the patient's responsibility to obtain either pre-authorization or referral. I understand that I may be held financially responsible for treatment, tests and/or procedures that are not reimbursed by my/the patient's insurance company or other payer due to lack of pre-authorization and/or referral, or as a result of the service/treatment not being a covered service, as stipulated in my/the patient's particular insurance policy.

Guarantee of Payment

By signing the form below, I understand and acknowledge that:

1. I am financially responsible for this account with, and for the fees associated with services I receive from my physician, regardless of any insurance benefits, to the fullest extent allowed by law.

2. I understand that I may be held responsible for any charges not covered for any reason by a third party payer. Should this account be turned over to a collection agency or an attorney for collection, I understand that I will be obligated to pay all collection fees and reasonable attorney's fees.

By signature below, I consent to and agree to the conditions set forth on this form. I have been given the opportunity to ask questions regarding this form, and understand the obligation I assume by signing this form.

Signature: _____

Printed Name: _____

Date: _____

Witness Signature: _____

Printed Name: _____