

Consent for Hormone Replacement Therapy

I, the undersigned, authorize and give my informed consent to Kay H Chandler, MD. for the administration of hormone replacement therapy.

ALTERNATIVES TO HORMONE REPLACEMENT THERAPY

I understand the reasonable alternatives to hormone replacement therapy, which include: Leaving the hormone levels as they are and doing nothing. Risks may include, but are not limited to: experiencing symptoms of hormone deficiency, and increased risk for aging-related diseases or dysfunction resulting from declining hormone levels. This alternative may result in the need to treat diseases or dysfunction associated with declining hormone levels as they appear clinically. Treating the symptoms of declining hormone levels as they develop with non-hormonal therapies.

Risks may include, but are not limited to: increased risk for aging-related diseases resulting from declining hormone levels

EXPECTED BENEFITS OF HORMONE REPLACEMENT THERAPY

- Expected benefits include control of symptoms associated with declining hormone levels.
- Possible benefits of this therapy may help prevent, reduce or control physical diseases and dysfunction associated with declining hormone levels, through hormonal replacement.
- Reduced incidence of hip fractures (also found in the WHI study) and improvement in bone health
- Reduced risk of colo-rectal cancer (also found in the WHI study)
- Potential improvement in sleep patterns, reduced risk of breast cancer (progesterone), decreased clotting risks (in avoiding oral estrogen products), improvement in cognition, improvement in libido, and weight loss (through improved metabolism).
- Medical science is always making new discoveries and developing new information. This could include the discovery of other significant advantages to me besides the ones listed above.
- I have been fully informed, and I am satisfied with my understanding, that this treatment may be viewed by the medical community as new, controversial, and unnecessary by the Food and Drug Administration.
- I understand that my healthcare provider cannot guarantee any health benefits or that there will be no harm from the use of hormone replacement therapy.

RISKS AND SIDE EFFECTS OF HORMONE REPLACEMENT THERAPY

Some of the following risks/adverse reactions are derived from the official Food and Drug Administration "FDA" labeling requirements for these drugs, for therapeutic drug levels in the blood stream. My healthcare provider may prescribe these medications at dosages designed to achieve physiologic levels of hormones in my blood stream or urine generally associated with those of a 20-35 year-old person and would be within the "normal" or "average" blood concentrations of that age group.

This authorization is given with the understanding that any treatment involves risks. I understand that it is not possible to anticipate all side effects or adverse outcomes. A study called the Women's Health Initiative (WHI) published in 2002, involving over 160,000 women between the ages of 50 and 79 determined some significant and substantial risks of this particular treatment, which are listed below. This study was done using traditional medical therapies (Premarin[®], MPA-Provera[®]) which are not chemically identical to what I will be using with Dr. Chandler, and in fact have significant adverse effects in and of themselves.

- Cardiovascular Disease: In the WHI the risk of heart attacks was increased in the group of women taking traditional combinations hormone therapy to 37 per 10,000 person-years, vs. 30 per 10,000 person-years in women who did not take hormone replacement therapy. This means that if 10,000 women took the combination hormone treatment medication in the study for 1 year, 37 of the 10,000 would have had a heart attack in that year, but 30 women who did not take hormone therapy 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 the combination hormone therapy vs. 30 per 10,000 person-years for similar women who did not take the hormone therapy.
- Strokes: The risk of stroke was 29 per 10,000 person-years for women taking the combination hormone therapy vs. 21 per 10,000 person-years for similar women who did not take the hormone treatment.
- Blood Clots (venous thromboembolism [VTE]): The risk of VTE was 34 per 10,000 person-years for women taking the combination hormone therapy vs. 16 per 10,000 person-years for similar women who did not take the hormone treatment. Medical science is always making new discoveries and developing new information. This could include the discovery of other significant risks to me besides the ones listed above.

GENERAL

I understand that the general risks of this proposed therapy may include, but are not limited to, bruising, soreness or pain, and possible infection for hormones administered by injection. I understand that there are risks (both known and unknown) to any medical procedure, treatment and therapy, and that it is not

possible to guarantee or give assurance of a successful result. I acknowledge and accept these known and unknown general risks.

ESTROGEN

A prescription hormone given by injection, orally or by transdermal cream or patch.

Risks associated with estrogen replacement include, but are not limited to: heart attacks, blood clot formation, gallstones, increased risk of uterine cancer (if progesterone is not administered with concurrently) and fibroid tumors. The Women's Health Initiative study demonstrated increased risk when estrogen replacement is initiated 10 or more years after menopause.

Estrogen replacement is not recommended in women with a history of the following conditions: breast or uterine cancer, phlebitis and blood clots, gall bladder disease, uterine fibroma, and liver disease.

Side effects may include, but are not limited to: increased body fat, fluid retention, uterine bleeding, depression, headaches, impaired glucose tolerance, and aggravation of migraines.

PROGESTERONE

A prescription hormone, given orally or by transdermal cream. Risks of progesterone replacement include, but are not limited to: Progestins are not the same as natural progesterone. Progestins may cancel the protective effect of estradiol, and promote constriction of the coronary arteries to a significant degree. Natural progesterone, on the other hand, may protect the endometrium, preserve the beneficial effects of estrogen on the cardiovascular system and exert no negative effects on the blood vessels that supply your heart. Progestins may cause birth defects, damage to nerve cells, blood clots, and breast cancer.

Side effects of progesterone replacement may include, but are not limited to: nipple or breast tenderness, drowsiness, fluid retention, slight dizziness, anxiety, difficulty sleeping, depression, acne, rashes, hot flashes, appetite increases and weight gain.

TESTOSTERONE

This is occasionally prescribed for women in low doses. Functions of testosterone include better memory, increased muscle mass, better sense of emotional well being, and an increase in sexual interest. We will usually consider adding testosterone to the mix after we have properly balanced estrogen and progesterone. If needed, testosterone can be added to your topical mix of estrogen and progesterone. It is usually used when a patient complains of low libido, despite other measures.

MY COMPLIANCE OBLIGATION WHILE RECEIVING HORMONE REPLACEMENT THERAPY</h3>

I agree to comply with the proposed treatment and therapy as prescribed, including the fact that I may be responsible for injecting, taking by mouth, applying to my skin, or administering the hormone(s) that may be prescribed to me, and consent to periodic monitoring, when requested, which may include:

- Laboratory monitoring of blood or urine chemistries and hormone levels
- Physical examinations
- Regular screening evaluations

I agree to notify you regarding all signs or symptoms of possible reactions to my therapy.

I agree to comply with all other healthy lifestyle activities that have been individually recommended for me. I have completely disclosed my medical history, including prescription and non-prescription medications that I am currently taking or plan to take during my treatment, as well as any other over-the-counter medications, recreational drugs or social substances, herbs, extracts, and other dietary supplements to you.

I agree to comply with the recommendations regarding the continuation or discontinuation of these preparations. In the future I will receive recommendations in advance from you before stopping any prescribed therapeutic regimens or taking additional preparations that are not recommended by you.

I certify that I am under the care of a physician(s) for any and all other medical conditions.

I certify that I have been given the opportunity to ask any and all questions I have concerning the proposed treatment, and I received all requested information and all questions were answered. I fully understand that I have the right to not consent to hormone replacement therapy. I believe I have adequate knowledge upon which to base an informed consent.

I do now attest to reading and fully understanding this form and the contents and clinical meanings of such, and discussing these procedures with my healthcare provider and consent to this treatment, and hereby affix my signature to this authorization for this proposed long-term treatment. I have been given a copy of this consent form, and I understand fully any and all of the possibly represented implications and meanings of its writing and expectations.

Signature

Date