Harmony Community Clinic
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Informed Consent: Hormone Therapy (Women)

Estrogen, progesterone, and testosterone; includes Controlled Substance Agreement for testosterone

Patient name (print) _____ Date of birth _____ Date _____

1. Treatment description

Hormone therapy is used to relieve symptoms of perimenopause and menopause, such as hot flashes, night sweats, sleep problems, vaginal dryness, and mood changes, and may help protect bone strength. The hormones recommended for me:

- ☐ Estradiol (patch, gel, cream, or pill)
- ☐ Vaginal estrogen
- ☐ Other: _____
- ☐ Progesterone
- ☐ Testosterone (low dose)

Product: ☐ FDA-approved ☐ Compounded. Compounded hormones (often called bioidentical) are not FDA-approved, and their strength may vary (see form HCC-10).

2. Alternatives

Alternatives include non-hormonal medications, lifestyle changes, vaginal moisturizers, or no treatment.

3. Risks of estrogen and progesterone

Recent FDA labeling updates (2025 to 2026) reflect evidence that, for many women who start hormone therapy before age 60 or within 10 years of menopause, the benefits often outweigh the risks. Risks still exist and depend on my age, the type and route of hormone, and my personal health history:

- Breast tenderness, bloating, headache, nausea, mood changes, and irregular bleeding or spotting.
- **Endometrial (uterine) cancer:** if I have a uterus, estrogen without progesterone increases this risk. I must take progesterone exactly as prescribed. I will report any vaginal bleeding after menopause.
- Blood clots and stroke, particularly with estrogen pills, smoking, or starting therapy after age 60.
- Breast cancer: long-term combined estrogen and progestin therapy has been associated with a small increase in risk in some studies.
- Gallbladder disease.

4. Risks of testosterone for women

There is no FDA-approved testosterone product for women in the United States, so its use is off-label. Possible effects include acne, increased facial or body hair, scalp hair thinning, changes in cholesterol, and, at higher levels, deepening of the voice and enlargement of the clitoris, which may be permanent. Blood levels will be monitored.

I have read and understand the risks listed above. _____ Initials

5. Screening questions

	Yes	No
Do you have unexplained vaginal bleeding?	☐	☐
Have you had breast, uterine, or ovarian cancer?	☐	☐
Have you had a blood clot, stroke, or heart attack?	☐	☐
Do you have liver disease?	☐	☐
Do you smoke?	☐	☐
Do you still have your uterus?	☐	☐

	Yes	No
Is your mammogram up to date?	☐	☐

Hormone therapy is not birth control. If I may still become pregnant, I will use reliable contraception. For patients who can become pregnant: I confirm that, to the best of my knowledge, I am not pregnant and not breastfeeding, and I will tell the provider right away if I become pregnant, plan to become pregnant, or begin breastfeeding.

6. Controlled Substance Agreement (testosterone only)

Testosterone is a Schedule III controlled substance. I will receive it only from this clinic, use one pharmacy, never share or sell it, keep it secure, complete monitoring labs, and understand that lost medication may not be replaced and that the clinic may check the Florida prescription monitoring database (E-FORCSE).

No guarantee: I understand that medicine is not an exact science. Results vary from person to person, and no promise or guarantee has been made to me about the results of this treatment.

Right to refuse or stop: I may refuse this treatment or stop it at any time. Stopping will not affect my right to receive other care at Harmony Community Clinic. Charges for services already provided or medications already dispensed still apply.

If I have a severe reaction, such as trouble breathing, swelling of the face or throat, chest pain, fainting, sudden vision changes, or severe pain, I will call 911 or go to the nearest emergency room right away, and then notify the clinic.

I consent to hormone therapy. _____ Initials

Signatures

By signing below, I confirm that I have read this form (or had it read to me) in a language I understand, that I had the opportunity to ask questions and all of my questions were answered, and that I agree to its terms voluntarily.

_____ Patient name (print)

_____ Patient signature

_____ Date

_____ Parent / guardian / legal representative (print, if applicable)

_____ Relationship to patient

_____ Representative signature

_____ Date

_____ Provider name and credentials

_____ Provider signature

_____ Date

Tell us about your visit

Your opinion helps other families find quality care. After your visit, scan this code with your phone camera to leave Harmony Community Clinic a review on Google.

Thank you for trusting us with your health.