BHRT consent form

Informed consent for bioidentical hormone therapy for menopause

TEMPLATE BY PABAU.COM

Please read each section. Tick each box to confirm you understand it, and ask your prescriber about any line that is unclear.

1. Patient and prescriber details

Patient name: _____ Date of birth: _____

Patient ID: _____ Date: _____

Prescriber name: _____ Prescriber credentials: _____

Practice name: _____

Supervising physician or medical director: _____

2. The hormones and routes prescribed

The prescriber completes this section before the patient signs.

☐ Estradiol: ☐ patch ☐ gel ☐ spray ☐ oral ☐ vaginal

☐ Micronized progesterone: ☐ oral

Other hormone: _____

Product type: ☐ FDA-approved product ☐ compounded preparation ☐ pellet (compounded)

Product name, or compounding pharmacy name: _____

Dose, route and schedule: _____

☐ My prescriber has explained the purpose of this treatment. I understand that results are not guaranteed.

3. FDA approval status of compounded hormones, pellets and creams

☐ Compounded hormone preparations, including compounded creams and pellets, are not FDA-approved. The FDA does not review their safety, effectiveness or quality before they are marketed.
Source: FDA compounded drugs page, June 22, 2026. Checked November 12, 2026.

☐ "Bioidentical" describes a hormone's chemical structure. The FDA has no evidence that compounded bioidentical hormones are safe and effective, or safer than approved products.
Source: FDA menopause page, December 14, 2023. Checked November 12, 2026.

☐ FDA-approved products containing estradiol and progesterone are available. My prescriber has discussed them with me.
Source: FDA menopause page, December 14, 2023. Checked November 12, 2026.

If a compounded preparation is prescribed, the medical reason (for example, an ingredient allergy or a dose no approved product offers): _____

Source: The Menopause Society 2022 position statement. Checked November 12, 2026.

☐ Hormone pellets are compounded preparations. If pellets are used, I will also sign a separate consent for the insertion procedure.

☐ If a compounded preparation becomes unavailable, my prescriber will discuss switching to another product with me.

4. Risks, in line with current FDA labeling

Risk	What the label says	Applies to	Source and date checked
Endometrial cancer	Estrogen without a progestogen raises endometrial cancer risk in a woman with a uterus. Adding a progestogen lowers the risk of endometrial hyperplasia.	Systemic estrogen alone, with a uterus. The boxed warning stays.	Sources: FDA labeling-change request, November 10, 2025 and Vivelle-Dot label, revised 10/2026. Checked November 12, 2026.
Blood clots and stroke	Increased risks of a clot in the lungs (PE), a clot in a deep vein (DVT) and stroke are reported.	All systemic estrogen	Source: Vivelle-Dot label, revised 10/2026. Checked November 12, 2026.
Heart attack	An increased risk of heart attack is reported with estrogen plus a progestin.	Estrogen plus a progestogen	Sources: Vivelle-Dot label, revised 10/2026 and Bijuva label, revised 2/2026. Checked November 12, 2026.
Breast cancer	An increased risk is reported with estrogen plus a progestin. My prescriber assesses my risk and arranges breast exams and mammograms.	Estrogen plus a progestogen (risk). All systemic estrogen (screening).	Sources: Vivelle-Dot label, revised 10/2026 and Bijuva label, revised 2/2026. Checked November 12, 2026.
Gallbladder disease	Estrogens increase the risk of gallbladder disease.	All systemic estrogen	Source: Vivelle-Dot label, revised 10/2026. Checked November 12, 2026.
Stop and call the practice	Estrogen is stopped if there is loss of vision, severe high calcium, pancreatitis linked to high triglycerides, or jaundice that returns.	All systemic estrogen	Source: Vivelle-Dot label, revised 10/2026. Checked November 12, 2026.

- ☐ Hormone therapy labels are being updated one product at a time. I will read the prescribing information for my own product.
  Source: FDA updated-labels list, current as of October 30, 2026. Checked November 12, 2026.
- ☐ Other side effects are listed in my product's prescribing information, and I will report any I notice.
- ☐ My prescriber has reviewed my age and time since menopause with me. The Menopause Society describes the benefit-risk ratio as favorable for women under 60, or within 10 years of menopause onset, without contraindications.
  Source: The Menopause Society 2022 position statement. Checked November 12, 2026.

5. Who should not start hormone therapy

Tick any item that applies to you. Your prescriber reviews every ticked item before prescribing.

- ☐ Vaginal bleeding that has not been diagnosed
- ☐ Current or past breast cancer
- ☐ A cancer that depends on estrogen
- ☐ Current or past blood clot in a leg vein or the lungs (DVT or PE)
- ☐ Active disease from clots in the arteries
- ☐ Liver problems (hepatic impairment)
- ☐ Protein C, protein S or antithrombin deficiency
- ☐ Known allergy to the product or its ingredients
- ☐ None of these apply to me

- ☐ Hormone therapy for menopause is not indicated for use in pregnancy. I will tell my prescriber if I am or could be pregnant.
  Source: Vivelle-Dot label, revised 10/2026. Checked November 12, 2026.

6. Monitoring the patient agrees to

- ☐ I will have a breast exam, a pelvic exam and a mammogram every year, unless my prescriber advises otherwise.
  Source: Vivelle-Dot label, revised 10/2026. Checked November 12, 2026.

☐ I will report any vaginal bleeding to the practice right away. Bleeding after menopause needs evaluation.
Sources: Vivelle-Dot label, revised 10/2026 and The Menopause Society 2022 position statement. Checked November 12, 2026.

☐ If I have a uterus and use systemic estrogen, I will take a progestogen as prescribed.
Source: The Menopause Society 2022 position statement. Checked November 12, 2026.

Follow-up visits and blood tests on my prescriber's plan: _____

☐ Saliva and urine hormone tests are not used to set my dose. The Menopause Society calls them unreliable and does not recommend them.
Source: The Menopause Society 2022 position statement. Checked November 12, 2026.

☐ Practice policy (edit or delete before use): Refills may be paused until my monitoring is up to date.

7. Alternatives, questions and the right to withdraw

Alternatives discussed with me: ☐ FDA-approved hormone therapy ☐ non-hormonal options ☐ no treatment

☐ I have had the chance to ask questions, and my questions were answered.

☐ I can withdraw this consent and stop treatment at any time by telling the practice. My prescriber will advise me on stopping.

☐ Treatment is billed to my insurance where it is covered, or paid directly. My insurer decides what it covers, and I pay any charges it does not.

8. Signatures, form version and date

I have read this form, or had it read to me. I consent to bioidentical hormone therapy as described above.

Patient signature: _____

Patient printed name: _____ Date: _____

I have explained the information on this form and answered the patient's questions.

Prescriber signature: _____

Prescriber printed name and credentials: _____

Date: _____

Witness signature and printed name (optional): _____

Form version: _____

Last reviewed with our medical director and legal counsel on: _____

Sources checked November 12, 2026.

For the practice: Review this form with your medical director and legal counsel before use, then fill in the version box.

Source addresses (all checked November 12, 2026)

1. FDA compounded drugs page, June 22, 2026: https://www.fda.gov/drugs/human-drug-compounding/understanding-risks-compounded-drugs
2. FDA menopause page, December 14, 2023: https://www.fda.gov/consumers/womens-health-topics/menopause
3. The Menopause Society 2022 position statement: https://menopause.org/wp-content/uploads/professional/nams-2022-hormone-therapy-position-statement.pdf
4. FDA labeling-change request, November 10, 2025: https://www.fda.gov/drugs/drug-alerts-and-statements/fda-requests-labeling-changes-related-safety-information-clarify-benefitrisk-considerations
5. Vivelle-Dot label, revised 10/2026: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5ccb77f9-d47b-4381-ad5c-5b92524e1c4a
6. Bijuva label, revised 2/2026: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/210132s013lbl.pdf
7. FDA updated-labels list, current as of October 30, 2026: https://www.fda.gov/drugs/drug-safety-and-availability/menopausal-hormone-therapies-updated-prescribing-information