

**HORMONE REPLACEMENT THERAPY****Patient Consent form Female**

Purpose: To offer Hormone Replacement Therapy (HRT), also called Menopausal Hormone Therapy (MHT) to peri- and postmenopausal women wishing to try it **WITH NO PRIOR HISTORY OF BREAST CANCER.**

Introduction

In 2002¹ and 2003², the Women's Health Initiative reports frightened millions of women, and their physicians, by claiming that postmenopausal HRT (estrogen + progesterone) for women with a uterus or estrogen alone for women who have had a hysterectomy) increased the risk of cardiovascular disease, dementia, stroke, death from all causes—and most alarming of all, that combination estrogen + progesterone (E+P) increased the risk of breast cancer. Understandably, prescriptions for hormone therapy plummeted.³ Since then, the WHI has retracted all of its early fears, maintaining only one: that E+P increases the risk of breast cancer, although it has not been shown to increase the risk of death from breast cancer. Even this claim has been seriously challenged in the medical literature, showing that it was a result of statistical error and mistaken interpretation.^{4,5,6}

¹ Rossouw JE, Anderson GL, Prentice RL, et al, Writing Group for the Women's Health Initiative Investigators. Risks and benefits of estrogen plus progestin in healthy postmenopausal women: principal results from the Women's Health Initiative randomized controlled trial. *JAMA* 2002;288:321-333.

² Chlebowski RT, Hendrix SL, Langer RD, et al. Influence of estrogen plus progestin on breast cancer and mammography in healthy postmenopausal women. The Women's Health Initiative Randomized Trial. *JAMA* 2003;289:3243-3253.

³ Brown S. Shock, terror and controversy: how the media reacted to the Women's Health Initiative. *Climacteric* 2012;15:275-80.

⁴ Kuhl H. Is the elevated breast cancer risk observed in the WHI study an artifact? *Climacteric* 2004;7:319-322.

⁵ Hodis HN, Sarrel PM. Menopausal hormone therapy and breast cancer: what is the evidence from randomized trials? *Climacteric* 2018;21:521-528.

⁶ Bluming AZ, Hodis HN, Langer RD. 'Tis but a scratch: a critical review of the Women's Health Initiative evidence associating menopausal hormone therapy with the risk of breast cancer. *Menopause* 2023;30:1241-1245.

I understand that the greater risk to women today is not breast cancer but heart disease, the

leading killer of women.^{7,8} Repeated studies have found that estrogen decreases the risk of cardiovascular events by 40% to 50%^{9,10}—more reliably than statins.^{11,12, 13,14,15}

Women need to be informed of the benefits of HRT as well as the risks.¹⁶

Benefits

⁷ Siegel RL, Miller KD, Jemal A. Cancer statistics, 2018. *CA Cancer J Clin.* 2018;68:7–30.

⁸ Cushman M, Shay CM, Howard VJ, et al. Ten-year differences in women's awareness related to coronary heart disease: results of the 2019 American Heart Association National Survey: a special report from the American Heart Association. *Circulation.* 2021;143:e239–e248.

⁹ Manson JE, Chlebowski RT, Stefanick ML, et al. Menopausal hormone therapy and health outcomes during the intervention and extended post stopping phases of the Women's Health Initiative randomized trials. *JAMA.* 2013; 310:1353–1368.

¹⁰ Schierbeck LL, Rejnmark L, Tofteng CL, et al. Effect of hormone replacement therapy on cardiovascular events in recently postmenopausal women: randomised trial. *BMJ.* 2021;345:e6409.

¹¹ Walsh JM, Pignone M. Drug treatment of hyperlipidemia in women. *JAMA.* 2004;291:2243–2252.

¹² Kendrick M. Should women be offered cholesterol lowering drugs to prevent cardiovascular disease? No. *BMJ.* 2007;334:983.

¹³ Brugts JJ, Yetgin T, Hoeks SE, et al. The benefits of statins in people without established cardiovascular disease but with cardiovascular risk factors: meta-analysis of randomised controlled trials. *BMJ.* 2009;338:b2376.

¹⁴ Petretta M, Costanzo P, Perrone-Filardi P, et al. Impact of gender in primary prevention of coronary heart disease with statin therapy: a metaanalysis. *Int J Cardiol.* 2010;138:25–31.

¹⁵ Yusuf S, Bosch J, Dagenais G, et al. Cholesterol lowering in intermediate-risk persons without cardiovascular disease. *N Engl J Med.* 2016;374:20212–20231.

¹⁶ Bluming AZ, Tavris C. Hormone Replacement Therapy: Real Concerns and False Alarms. *The Cancer Journal* 2009;15:93-104.

1. In addition to reducing the incidence of heart disease,¹⁷ HRT has been shown to decrease the risks of osteoporosis,^{18,19} colon cancer,^{20,21,22} cognitive decline,^{23,24} and diabetes^{25,26} in postmenopausal women.

2. The primary benefits of HRT on peri and menopausal symptoms among all women, as well as survivors of breast cancer, include, but are not limited to, eliminating or reducing hot flashes, mood swings, dry skin, dry mucous membranes, frequent burning on urination, repeated urinary tract infections, vaginal dryness, weight gain around the abdomen, heart palpitations, muscle and joint pain, loss of sexual desire and painful sexual intercourse, sleep disorders, and “brain fog” or other memory impairments. Although HRT is widely accepted as the most effective treatment of these symptoms,^{27,28} I understand they may not be alleviated by the hormone replacement therapy I receive.

Risks

1. I understand that the risk of cancer of the uterine lining may be increased by the use of estrogen therapy alone, but that the addition of progesterone eliminates this increased risk. The

¹⁷Flores VA, Pal L, Manson JE. Hormone therapy and menopause: concepts, controversies, and approach to treatment. *Endocrine Reviews* 2021;42:720-52.

¹⁸Cauley JA, Robbins J, Chen Z, et al. Effects of estrogen plus progestin on risk of fracture and bone mineral density. The Women's Health Initiative Randomized Trial. *JAMA* 2003;290:1729-38.

¹⁹Langer RD, Simon JA, Pines A, et al. Menopausal hormone therapy for primary prevention: Why the USPSTF is wrong. *Climacteric* 2017;20:402-13.

²⁰Calle EE, Miracle-McMahill HL, Thun MJ, et al. Estrogen replacement therapy and risk of fatal colon cancer in a prospective cohort of postmenopausal women. *J Natl Cancer Inst.* 1995;87:517–523.

²¹Persson I, Yuen J, Bergkvist L, et al. Cancer incidence and mortality in women receiving estrogen and estrogen-progestin replacement therapy— long-term follow-up of a Swedish cohort. *Int J Cancer.* 1996;67:327–332.

²²Slattery ML, Anderson K, Samowitz W, et al. Hormone replacement therapy and improved survival among postmenopausal women diagnosed with colon cancer (USA). *Cancer Causes Control.* 1999;10:467–473.

²³Espeland MA, Rapp ST, Shumaker SA, et al. Conjugated equine estrogens and global cognitive function in postmenopausal women. Women's Health Initiative Memory Study. *JAMA* 2004;291:2959-68.

²⁴Matyi JM, Rattinger GB, Schwartz S, et al. Lifetime estrogen exposure and cognition in late life: the Cache County study. *Menopause.* 2019;26:136–174.

²⁵Bonds DE, Lasser N, Qi L, et al. The effect of conjugated equine oestrogen on diabetes incidence: the Women's Health Initiative randomised trial. *Diabetologia.* 2006;49:459–468.

²⁶Lobo RA, Davis SR, De Villiers TJ, et al. Prevention of diseases after menopause. *Climacteric.* 2014;17:540–556.

²⁷Pines A. Guidelines and recommendations on hormone therapy in the menopause. *J Midlife Health.* 2010;1:41–42.

²⁸Crandall CJ, Mehta JM, Manson JE. Management of menopausal symptoms. A review. *JAMA* 2023; 329:405-20. addition of progesterone may also decrease the protective effect of estrogen alone against the risk of heart attack or stroke. I realize that progesterone will not be used if I have had a hysterectomy.

2. I understand that the development of breast cancer is possible with or without hormone replacement therapy and that taking hormones may, in spite of my physician's current understanding and best efforts, increase that risk.

3. I understand that I may experience some side effects of hormone replacement therapy.

These might include vaginal bleeding or spotting (which may require further investigation such as an endometrial biopsy or a D&C), fluid retention, painful breasts, jaundice, skin rash, intolerance to contact lenses, headache, depression, or thrombophlebitis (clot formation). I will immediately report any of these or other signs or symptoms while on HRT to my doctor.

I have been made aware of and agree with the following statements:

1. I am currently peri- or postmenopausal.
2. I will take the hormone replacement therapy as prescribed by my doctor and will keep all scheduled follow-up appointments to the best of my ability.
3. My physician remains available to answer any additional questions I have about this course of action.

Signed:

_____ date _____ Print name:
