

**ARISTA OB/GYN CONSENT FOR HORMONE REPLACEMENT THERAPY**

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**Women's Health Initiative Study from the National Heart, Lung & Blood Institute July 17, 2002**

Recently, a great deal of publicity and concern has been generated by the results of the Women's Health Initiative (WHI) study. This study evaluated the safety of hormone replacement therapy (HRT) in post-menopausal women. We hope this short summary will help you better understand these results, so you can make informed decisions about HRT. Although the increase in breast cancer and cardiovascular disease is real, the magnitude of the risk is small for individual women.

**What did the Women's Health Initiative Study show?**

In the WHI, over 16,000 women (ages 50-79) participated for 5 years. During that time, about half the women took a combination of estrogen and progesterone HRT (the PREMPRO™ brand,) and the others did not take HRT. These women did not have other symptoms of menopause. Recently, the authorities in charge of the study decided to stop the study because the benefits of continuing the study did not justify the risks posed to the study participants. The WHI estimates of the risks and benefits of HRT are summarized below:

► Cases each year in 10,000 women:

	<u>NOT using HRT</u>	using HRT	Risk Rate
Women developing heart disease	30	37	1.29
Women developing breast cancer	30	38	1.26
Women developing strokes	21	29	1.41
Women developing blood clots	16	34	2.13
Women developing bone fractures	15	10	0.66
Women developing colorectal cancer	16	10	0.63

**What does this mean for me?**

Women use HRT for many reasons. Most women use HRT to reduce hot flashes and night sweats, to improve mood and sleep patterns, and to prevent vaginal dryness and irregular vaginal bleeding. Improved bone health and prevention of osteoporosis also play a role in the decision to use HRT. Some women just feel better on HRT than they do without HRT. All of these can improve a woman's daily "quality of life," benefiting not only her, but her family and friends as well. These benefits should be considered along with the risks when you and your physician discuss whether to start or continue HRT.

Unfortunately, many questions about HRT remain. For example, we do not know: --if the WHI results apply to all forms of HRT or just to PREMPRO™.

--whether the increased risks come from the estrogen part, the progesterone part, or the combination of the two.

--if estrogen alone has fewer risks than estrogen/progesterone combinations.

► Given the results of the WHI study, you have several options regarding HRT:

- 1) use no hormone replacement therapy.
- 2) use medications other than hormones for menopausal symptoms.
- 3) use hormone replacement therapy other than PREMPRO™.
- 4) use PREMPRO™ for hormone replacement therapy.

Please feel free to contact us with your questions. We will be happy to discuss these important issues with you.

I have read and understand the above information and I have had all my questions answered. I understand that there are risks and benefits to taking hormone replacement therapy and that no guarantees or assurances have been made to me concerning the above procedure or treatment. For more information go to [www.nhlbi.nih.gov](http://www.nhlbi.nih.gov)

Signed: \_\_\_\_\_ Date: \_\_\_\_\_ Provider: \_\_\_\_\_