Patient Education Information and Informed Consent for Hormone Replacement Therapy

Dr. ___________________________ has discussed the following combination hormone replacement therapy (HRT) with me: __________________________________________________________

1) TREATMENT ALTERNATIVES

I understand that one alternative is simply NOT to take hormone replacement therapy. Other treatment alternatives include: __________________________________________________________

The possible risks of alternative treatment, if any include: __________________________________________________________

2) RISKS OF HORMONE REPLACEMENT THERAPY

This authorization is given with the understanding that any treatment involves risks. I understand that it is not possible to anticipate all side effects. A study called the Women’s Health Initiative, published in 2002, involving over 160,000 women between ages of 50 and 79, determined some significant and substantial risks of this particular treatment, which are listed below. I understand the risks to me as an individual vary greatly and can be greater or less than those found in this or other studies.

   Cardiovascular Disease: The risk of heart attacks was increased in the group of women taking combination hormone replacement to 37 per 10,000 persons-years vs. 30 per 10,000 person-years in women who did not get the combination hormone therapy. This means if 10,000 women took the medication for 1 year, 37 of 10,000 who took the combination hormone would have had a heart attack in that year, but 30 of the 10,000 who did not take the hormone 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 combination hormone therapy vs. 30 per 10,000 person-years for similar women who did not take the hormone.

   Strokes: The risk of stroke was 29 per 10,000 person-years for women taking combination hormone therapy vs. 21 per 10,000 person-years for similar women who did not take the hormone.

   Venous Thromboembolism (blood clots): The risk of venous thromboembolism was 34 per 10,000 person-years for women taking combination hormone therapy vs. 16 per 10,000 person-years for similar women who did not take the hormone.

Medical science is always learning new information; this could include the discovery of other significant risks to me besides the ones listed above.

The risks listed here represent the most common significant risks, but others may exist.

Other potential risks to me include: __________________________________________________________
3. **BENEFITS OF HORMONE REPLACEMENT THERAPY**

My physician and I have discussed the potential benefits to me of taking combination hormone replacement therapy, including the potential relief of menopausal symptoms. Additionally, the Women’s Health Initiative study found the following benefits to taking combination hormone replacement therapy:

**Reduced Incidence of Hip Fractures:** Women who took the combination hormone therapy had lower risks of hip fractures (10 per 10,000 person-years of women who took HRT got hip fractures, while 15 per 10,000 person-years of women who did not take HRT got hip fractures).

**Reduced Incidence of Colorectal Cancer:** Women who took the combination hormone therapy had lower risks of colorectal cancer (10 per 10,000 person-years of women who took HRT got colorectal cancer, while 16 per 10,000 person-years of women who did not take HRT got colorectal cancer).

Other potential benefits to me include: ___________________________________________________________________________

___________________________________________________________________________________________________________________________________________

Medical science is always learning new information; this could include the discovery of other significant benefits to me besides the ones listed above.

If you have any questions as to the risks and benefits of the proposed treatment or any questions concerning the proposed treatment, ask your physician now before signing this consent form.

Do not sign unless you have read and thoroughly understand this form.

4. **PATIENT’S CONSENT**

I have read and fully understand this consent form. I understand I should not sign this form if the treatment, the alternatives, and the risks and the benefits have not been explained to my satisfaction. I further understand that I should not sign this form if I have unanswered questions or if I do not understand any of the terms or words used in this consent form.

I give my consent to the administration of the above named medications.

__________________________________________________________________________  ________________

*Patient/responsible party*  *Date*

__________________________________________________________________________  ________________

*Witness*  *Date*

5. **PHYSICIAN DECLARATION**

I have explained the contents of this document to the patient and have answered all the patient’s questions, and to the best of my knowledge, I believe the patient has been adequately informed and has consented.

__________________________________________________________________________  ________________

*Physician*  *Date*