

## Informed consent for Hormone Replacement Therapy

Because of the rapidly changing understanding about the safety and effectiveness of hormone therapy for anything other than birth control, we feel it is important to be sure that you have information about the risks and benefits of hormone therapy before you take the therapy we have discussed.

Hormone replacement therapy (HRT) is often prescribed to women during perimenopause (the time before and after your last period when symptoms occur) and menopause (the time of your last period onward) for symptoms of hot flashes, vaginal dryness, loss of libido, depression, anxiety, irritability or PMS like symptoms, bone loss, osteoporosis or its prevention, and cardiovascular disease. HRT is only approved by the FDA for use treating hot flashes and osteoporosis. Using it for other symptoms or problems is considered "off-label" use and the burden is on the practitioner to be sure that there is adequate science to support the use in a given situation.

At Calmglow we do everything we can to decrease the risks of hormone replacement. Our goal is to return your hormones to normal levels for your age, using hormones that are identical to the ones your body makes (called bio-identical hormones). Your practitioner may prescribe synthetic hormones or drugs that mimic these hormones in certain situations as needed.

Since the Women's Health Initiative (WHI) study came out, it has been thought that the combination of estrogen and progestogens (progesterone or artificial progestins such as Provera) increase the risk of breast cancer more than the risk of estrogen alone. Orally administered combination hormones also increase the risk of blood clotting and therefore heart attacks and strokes. While bio-identical hormones may decrease these risks, the relationship of HRT and breast cancer is complex and controversial. Hormone replacement decreases the risk of osteoporosis and may decrease the risk of colon cancer. In the low doses usually needed to bring your hormone levels back to normal, many of the risks may be diminished or disappear.

Estrogen only replacement therapy (ERT) is used primarily for women who have had their uterus removed and who do not have any negative symptoms with estrogen alone. In these women very low doses of estrogen alone may be used without progestagen if adrenal function is healthy. When higher doses of estrogen are used or adrenal function is not ideal there is a risk of bleeding, endometrial hyperplasia or cancer and you should discuss this with your practitioner if you are not taking progesterone.

When hormone levels are brought back to 'normal' for your age, there is evidence that your overall health improves. For instance, the risk of osteoporosis and fractures decrease and your life span in some cases may increase.

HRT is the most effective treatment for hot flashes. There may be other long-term beneficial effects of treatment. If your (female sex) hormones are already normal however, adding additional hormones to address symptoms such as hot flashes may increase your risk of diseases like cancer or problems like blood clotting.

The current medical thinking is always changing so it is important to discuss HRT with your practitioner each year at your annual exam to find out what the latest thinking is. Be aware that as the scientific evidence increases our recommendations may change.

We will want to check your hormone levels before putting you on hormones and will recommend appropriate times to re-check your levels after starting therapy. It is important to do these tests properly and to take your hormone consistently. We will require an annual exam and regular mammograms as this allows us to be sure hormones are still the safest options for you.

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### **Please read the following and sign:**

I have discussed the reasons for taking female sex hormone with my practitioner and understand why he/she is prescribing them, and the risks associated with taking hormones, including but not limited to the possibility of an increased risk of breast or endometrial cancer, blood clotting stroke or heart attack.

I understand there are different risks if I take progestogens or testosterone and they may be higher or lower than taking estrogen alone. I have discussed this risk and the reasons for taking them with my practitioner.

I understand that my practitioner will do everything he/she knows to do to decrease and minimize the risks of HRT but that there are no guarantees that these measures will be effective in preventing the negative side effects mentioned above or other side effects that we do not yet know about.

I accept the risks and unknowns of taking hormone therapy and wish to have my practitioner prescribe them for me

Signed \_\_\_\_\_ Date \_\_\_\_\_