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**CONSENT TO TREAT & NOTICE OF OFF-LABEL USE**  
**SAFETY OF HORMONE REPLACEMENT & OFF-LABEL DRUG USE**

What is considered off-label drug/prescription use?

1. It is considered off-label use/alternative medicine if you are on any compounded form of medication. Please note that compounded medications do not meet FDA approval and therefore are considered off-label.
2. It is considered off-label use/alternative if you are on a medication which is being used outside of the medication labeling offered by the package insert.

Drug labels are specific to the disease they treat and therefore if the medication is used to treat a disease that is not specified in the label, then the agent is being used off-label. Additionally, any change to the approved dose, frequency or route of administration would constitute an off-label use.

The use of off-label medications is common practice among the medical community and while we are not legally required to obtain a signed written consent it is the belief of this practice that the patient be fully aware of the current treatment plan recommended including its risks, benefits and alternatives to your plan of care. Remember that even over the counter medications carry risks when taken. It is our belief that the treatment of hormone deficiencies can be of great benefit in improving quality of life

Medications and supplements which may be used off-label or as alternative medicine can include but are not limited to the following:

armour thyroid, estriol, estradiol, progesterone, DHEA, and/or testosterone in compounded formulations. The use of supplements may also be used in an effort to help improve conditions and or symptoms that you may have presented with during your initial consultation and throughout the course of your visit.

If you experience any side effects associated from current prescribed medications, please call the office immediately. If it is after usual business hours and you should have severe side effects, please proceed to the nearest emergency room or urgent care facility for appropriate treatment.

While hormone therapy will not cause cancer, the use of hormones could potentially make an estrogen and/or progesterone positive cancer grow. Most breast cancers fall into this category.

As a patient you have the right to refuse any off-label use of the medication being prescribed. You also have the right to ask questions regarding the current treatment plan as well as alternatives to what is being prescribed. If you have any questions or concerns, please make sure to discuss this with your provider during your consultation and any future visits.

### FEMALE PATIENTS DESIRING HORMONE REPLACEMENT

The reasonable alternatives to this treatment have been explained to me and they include:

1. Leaving the hormone levels as they are.
2. Treating age-related diseases as they appear.
3. Using pharmaceutical agents that are not bio-identical in nature.

Possible side effects for women on estrogen, progesterone and/or testosterone (in any method of delivery) include: breast swelling or discomfort, fluid retention, dizziness, break through bleeding, acne, unwanted hair growth, headaches, increased risk of heart attack, stroke and other cardiovascular problems, increased risk of gallbladder disease, increased risk of blood clots, worsening of ovarian cysts, uterine fibroids, endometriosis, and fibrocystic disease.

Contraindications: Do not use hormone replacement if you have a known history of reproductive system related cancers such as breast cancer, ovarian cancer, uterine cancer. Exceptions include reproductive system responsive cancer which has been under remission for over 5 years.

I also understand that if I am female and become pregnant, I should stop the entire treatment protocol immediately and notify my primary physician. I understand that this hormone therapy is not for the purpose of preventing pregnancy, and that if I become pregnant on this therapy it could present risk to the fetus (unborn child).

I have provided the office with a copy of my most recent pap and mammogram (if these tests were not completed by this office) and the results are within one year of this appointment.

\_\_\_\_\_(Initial) I understand the possible treatments and side effects

## ALL PATIENTS: OBLIGATIONS & REPRESENTATIONS

Any questions I have regarding this treatment have been answered to my satisfaction. I will comply with the recommended dose and methods of administration. I also agree to participate in the initial and subsequent blood testing as required to monitor my hormone levels.

I have disclosed accurate and true information regarding my medical history, medications, and surgeries.

I certify that I am under the regular care of a physician for all other medical conditions. I will consult my primary care physician(s) for any other medical services I may require. I also understand that I will continue under the care of my other physician(s) for any on-going medical condition as well as for any medical consultation that I may need.

I assume full liability for any adverse effects that may result from the non-negligent administration of the proposed treatment. I waive any claim in law or equity for redress of any grievance that I may have concerning or resulting from the therapy, except as that claim pertains to negligent administration of the therapy.

I fully understand the nature and purpose of portions of the aforementioned treatment may be considered experimental because of the lack of adequate scientific evidence or peer-reviewed publications supporting the underlying premise of bio-identical hormone replacement therapy and that such therapy might even be considered by some medical professionals to be medically unnecessary because it is not aimed at treating a particular disease.

I understand that I may suspend or terminate treatment at any time and hereby agree to immediately notify the physician of any such suspension or termination.

I also understand there are possible benefits associated with this therapy but that no guarantee has been made to me regarding the outcomes of this treatment. I also understand that the benefits derived from antioxidant therapy, hormone therapy and drugs that alter hormone levels will cease or reverse if the therapy is discontinued.

**ALL PATIENTS: CONSENT**

I hereby authorize my physician to evaluate and treat the conditions I specified above. I understand that my physician may be assisted by other health professionals, as necessary, and agree to their participation in my care as it relates to the evaluation and treatment of the conditions this Consent to Treat covers. I am competent to sign this Consent to Treat and have done so of my own free will.

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Printed Name of Patient

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Signature of Patient

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Date

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Witness Print/Signature