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Wiley Protocol Consent Form

INFORMED CONSENT FOR TAKING NON-FDA APPROVED DOSES OF FDA APPROVED HORMONE REPLACEMENT THERAPY FOR MENOPAUSE SYMPTOMS

I request and consent to treatment with Wiley Protocol Estradiol ____, Wiley Protocol Progesterone ____, Wiley Protocol Testosterone ____, Wiley Protocol for Men ____, Wiley Protocol Melatonin____, and/or Wiley Protocol Face Creme ____ (please initial) for the purpose of correcting hormone deficiencies and imbalances. I understand that initial blood tests may be performed to rule out any conditions that would disqualify me from the program, require any prior treatment before starting the program, or require closer monitoring during the program.

Potential Side Effects and Risks

Properly prescribed, properly dosed, and properly monitored bioidentical hormone replacement therapy is virtually free of negative side effects, but because of individual variability and sensitivity to hormones patients may experience certain symptoms.
With any drug there is the possibility of an allergic reaction or unusual reaction that may cause a skin rash, difficulty breathing, collapse, or even death.

I agree to immediately report any problems that might occur to Dr. Austin during the treatment program. I further understand that there could be risks involved as there are with all medications and that not complying with the dosage recommendations and other treatment recommendations could increase risks and alter the results.

Monitoring and Follow Up

I understand that the Wiley Protocol will be prescribed and monitored by Dr. Kelly Austin.
I agree to the following:

- A comprehensive review of my medical history and thorough physical examination.
- Laboratory testing as recommended by Dr. Kelly Austin
- To monitor and document my symptoms on the Wiley Protocol Lunar or Personal Calendar as applicable
- To report any of the following immediately by e-mail AND telephone: worsening signs and symptoms, and any unexplained complaints and potential side effects
- To follow up in the office at least once every three to six weeks, or more often, depending on my specific needs
- To comply with dietary, lifestyle and treatment recommendations
- To follow instructions for monitoring any other parameters such as blood pressure, pulse, serum glucose levels, and laboratory testing, as applicable to the patient's medical condition
- To follow standard of care and have regular mammograms and/or ultrasounds with my general practitioner as recommended.

Women Must Stop Treatment When Pregnant

Notice to all pregnant women: All female patients must alert Dr. Austin immediately if they know or suspect that they are pregnant.

No Guarantee of Results

I understand that results may vary and once I have begun the protocol I am committed to following through.

I understand that the protocol and the hormones may involve risk. I understand that there are no refunds, returns or store credit for hormones, nutritional supplements, or medical consultations. I understand there is no weight loss guarantee with this program. I have read and understand the information given to me about the hormones. I have asked and had answered any questions that I may have after reading this form. I understand the possible side-effects and agree to advise Dr. Austin's office should they occur. I understand that I may quit the protocol at any time. I agree to stop the protocol if I become pregnant and agree to advise the office should I decide to become pregnant. No adverse side effects or complications are expected, but in the event that an illness does occur, I understand that I need to contact the office. If I experience an emergency situation, I understand that I need to go to an emergency facility.

I realize that Dr. Austin cannot offer any absolute guarantees to me regarding cure or improvement of my condition. I understand that I am free to withdraw my consent and discontinue treatment at any time.
By signing below, I understand that I am agreeing to take FDA approved hormones for the treatment of menopausal symptoms. I have been fully informed that the doses I am agreeing to take are not FDA approved for the treatment of menopausal symptoms.

I am aware that there may be benefit of these doses as noted in the book, *Sex, Lies and Menopause*, by T. S. Wiley, Julie Taguchi, M.D. and Bent Formby, PH.D. However, I also have been fully informed of the potential risks of these different hormone replacement doses. I understand that there are no clinical trials on these doses.

I am aware that the Women's Health Initiative Study found that "hormone replacement therapy" (of non bio-identical synthetics) for long term use after menopause may cause harm. This harm could include heart attacks, dementia, strokes, breast cancer, blood clots, pulmonary embolism (blood clots to the lungs), gallbladder attacks, and even sudden death.

By signing below, I agree that I have been fully informed of my potential risks and benefits. I consent to take these non- FDA approved doses of FDA approved hormone and agree to be closely monitored. This is my freedom of choice for my healthcare.

YOUR SIGNATURE BELOW INDICATES THAT YOU HAVE READ THE INFORMATION ABOVE, HAVE HAD YOUR QUESTIONS ANSWERED, HAVE HAD POTENTIAL SIDE EFFECTS EXPLAINED, AND AGREE TO NOTIFY DR. AUSTIN'S OFFICE OF ANY CHANGE IN YOUR HEALTH STATUS OR MEDICATIONS PRESCRIBED. I CERTIFY THAT I UNDERSTAND THE PROTOCOL AND I WILL FOLLOW IT STRICTLY.

Print Patient Name: _____ **Sign:** _____ **Date:** _____