

## **SALLY KRAYNIK NP LLC**

### **INFORMED CONSENT FOR GENDER-AFFIRMING HORMONE THERAPY CARE AND TREATMENT**

Before you decide to take gender-affirming hormone therapy (GAHT), it is important for you to know what it is and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Please ask Sally Kraynik, NP if there is anything that is not clear, or if you would like more details. Your consent to this form indicates that you received all the information below, and that you know you can and should discuss any questions and concerns you have with Sally Kraynik, NP before deciding whether or not to take GAHT.

#### **Sally Kraynik, NP, WPATH GEI SOC8 Certified Member**

Your treating provider, Sally Kraynik, NP is trained and certified in GAHT by the World Professional Association for Transgender Health (WPATH) and follows established GAHT guidelines and standards of care. Sally Kraynik's telemedicine practice is devoted to serving the transgender and gender diverse community seeking support and gender-affirming medical treatment. In your initial appointment, Sally Kraynik, NP will perform an assessment and establish a treatment protocol using GAHT, as clinically appropriate. You may be required to obtain laboratory work to monitor the GAHT effects, as well as present for follow-up appointments with Sally Kraynik, NP. As with any medical treatment, there are risks and benefits associated with that treatment, described below. Prior to initiating GAHT with Sally Kraynik, NP, you will be required to read and consent to the detailed Fenway Health Risks and Benefits of GAHT, but some risks and benefits are described below.

**1. RISK/SIDE EFFECTS OF GAHT.** Testosterone hormone therapy side effects can include but are not limited to: increased number of red blood cells and high blood pressure. Estrogen hormone therapy side effects can include but are not limited to: blood clot and stroke.

**2. BENEFITS OF GAHT.** GAHT can improve your mental health, body image, and self-esteem, thereby experiencing a greater sense of alignment between your gender identity and physical appearance, improvement in social and family relations, and an overall improvement in your quality of life.

#### **3. PATIENT CONSENT**

- I agree to be under the care of Sally Kraynik, NP for GAHT.
- I know that my taking part in GAHT is my choice.
- I know that I may decide not to take GAHT at any time.
- I also know that GAHT may not help my underlying diagnosis, or I might experience side effects.
- I will not start taking GAHT until I have had a chance to ask Sally Kraynik, NP questions about GAHT, and those questions have been answered to my satisfaction.
- I will not start taking GAHT until I am satisfied that the possible alternative methods of treatment, the risks involved, and the possibility of complications have been fully explained to me.
- No guarantees or assurances have been made or given to me about the results that may be obtained.

## Risks and Benefits of Estrogen and Spironolactone

**The goal of this form is to provide the most up to date information about the expected effects of hormone therapy, including both the desired effects as well as possible unwanted side effects. You should have the information you need to make decisions about your care. Please do not hesitate to ask questions and talk about any concerns you have at any time.**

Estrogen treatment (usually estradiol) results in certain changes to the body that some people find affirming, including softening of the skin, decreased muscle mass, changes in facial and body hair, fat redistribution, and breast growth. Some also use an androgen blocker, a medication that can reduce or block the effects of testosterone and can sometimes enhance the effects of estrogen. Each person responds to hormones differently, and it is difficult to predict some aspects of how your body might change.

Hormone therapy will not change certain body features. Bone structure and height will not change, and the Adam's apple will not shrink. The pitch of the voice also will not change. Hormone therapy is not the only way to achieve your goals - we can always talk about other options (such as non-medical affirming products, other medications, and/or surgeries) that might be right for you.

You and your medical provider will review which formulation and dose of estrogen (oral tablets, injections, topical gels, patches) and/or androgen blocker may be best for you based on your gender affirmation goals, personal needs, and any medical or mental health conditions you might have. As part of this treatment, you agree to take the medications only as prescribed and to talk with your medical provider before making any changes in your medication. You and your medical provider can work together to best support your goals for care as safely as possible.

Fenway has worked with gender diverse people for many years. Our approach to gender affirming care is based on scientific evidence whenever possible, national and international guidelines, and the feedback and experience we get from our own gender diverse community. Continuing research on gender affirming hormone therapy provides us with more information on the safety and effectiveness of these medications in helping you to achieve your goals. Despite the available research, the long-term effects of hormone therapy across the lifespan are not yet fully understood. This document outlines what we currently know about these medications. We will pass along any new information or research we learn, especially as it affects your health and wellbeing.

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### Expected Physical and Emotional Effects of Estrogen Therapy

The changes in your body may take several months to become noticeable and may take up to 3 to 5 years to progress fully.

Some changes are PERMANENT and will not go away, even if you decide to stop taking estrogen or take a lower amount:

- Breast growth and development. Breast size on estrogen therapy varies greatly. Taking estrogen often leads to breast growth and tenderness. Breast size tends to reach full potential after 1-2 years of continual estrogen therapy, and many people report breast size around an A or B cup. Breasts may look smaller on broader chests. If you stop taking estrogen your breasts may decrease in size, but will not go away completely.

Some changes are **NOT PERMANENT** and will likely return to the way your body looked or worked before treatment if you stop taking estrogen and/or an androgen blocker. This may take a few weeks to months or longer depending on the change:

- Loss of muscle mass and decreased strength, particularly in the upper body.
- Decreased metabolism and weight gain. If you gain weight, the fat will tend to localize, or redistribute, more typically in the buttocks, hips, and thighs.
- Skin may become softer, drier, and existing acne may decrease.
- Facial and body hair will get softer and lighter and grow more slowly, but will not go away
- Hair loss at the temples and crown/top of the head (androgenic alopecia) may slow down or stop, but hair will typically not regrow.
- Changes in mood or thinking may occur; some people may feel increased emotional reactions and others may feel more balanced or less emotional.
- Sex drive may decrease. This can range from a very slight change, to a much more significant decrease.
- Decreased strength of erections or inability to get an erection. The ejaculate may become thinner and watery and there will be less of it. Over time, ejaculate may completely disappear.
- The testicles will get smaller, softer, and will produce less sperm.

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### Possible Fertility Effects of Estrogen Therapy and Decreased Testosterone

- The ability to get someone pregnant may decrease significantly or stop (infertility). The time this takes and whether infertility becomes permanent varies greatly from person to person. Fertility may or may not return after stopping estrogen.
- Possible loss of fertility; you may not be able to get someone pregnant after being on estrogen therapy for some time. How long this may take is unknown. Even if you stop taking estrogen, fertility may not come back. Whether this becomes permanent is difficult to predict. Some people choose to bank sperm before starting estrogen.
- Estrogen therapy is not a method of birth control. There is no way to predict when or if a person will become infertile (unable to get someone pregnant) when taking estrogen. Other birth control methods will be necessary (condoms, oral contraceptives, etc.) to prevent pregnancy if you are having any type sex that could result in a pregnancy.

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### Possible Side Effects and Risks of Estrogen Therapy

- Brain structures respond differently to testosterone and estrogen. Estrogen therapy may have long-term effects on the functioning or structure of the brain that we do not yet fully understand.
- Possible increased risk of developing blood clots. Risks are uncertain overall, with higher risks in those with a family or personal risk of blood clots, those with certain underlying health conditions, and those using high doses of certain forms of estrogen. Risks include developing blood clots in the legs or arms, in the lungs, or in the arteries, including the arteries of the brain. Blood clots in the lungs, heart, or brain could result in death. Research suggests lower cardiovascular risk (risk of blood clots, strokes, and heart attacks) with the use of transdermal estrogen (patches or gel).
- Possible increased risk of heart attack or stroke. This risk may be higher if you use tobacco products, are over age 45, or already have high blood pressure, high cholesterol, diabetes, or a family history of cardiovascular disease, and if you have low physical activity.
- Possible increase in blood pressure requiring treatment with medication.
- Possible increased risk of developing diabetes. Limited research has found an increase in insulin resistance in people taking estrogen therapy. The effect of estrogen therapy on the risk of developing or on the management of diabetes remains unclear.
- Possible nausea and vomiting, especially when first starting on estrogen therapy.
- Possible increased risk of gallbladder disease and gallstones.
- Estrogen may lead to liver inflammation and/or contribute to existing liver damage.
- May cause or worsen headaches and migraines. Migraine headaches have a clear hormonal element. Estrogen may increase the intensity or frequency of migraines.
- May cause elevated levels of prolactin (a hormone made by the pituitary gland). It remains rare, but a few people taking estrogen for hormone therapy have developed prolactinomas, a benign tumor of the pituitary gland that can cause headaches and problems with vision as well as other hormone problems.
- Some people may feel their mental health and social comfort improves, and others may feel it worsens. While affirmation of gender is associated generally with improved mental health outcomes, the effect of estrogen therapy on specific mental health conditions is unknown. There is no clear evidence that estrogen therapy is directly responsible for causing or making any mental health condition worse. If you have a history of mental health diagnoses, discuss these with the clinic staff to explore which supports and services may be best to meet your needs.
- Risks of breast cancer are unclear. The risk may be higher than that in cisgender men, but does appear significantly lower than the rates seen in cisgender women. Risk factors include family and genetic history of breast cancer, length of time on estrogen therapy, age when starting estrogen therapy, and possible exposure to progesterone.
- If you develop enough breast tissue and are over the age of 50, your provider will recommend breast cancer screenings following similar guidelines as those recommended for cisgender women.

*Smoking, inhaling second-hand smoke, and use of tobacco products may greatly increase the risks of taking estrogen therapy, especially the risk of blood clots and cardiovascular disease.*

## Risks and Benefits of Estrogen and Spironolactone

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### **Risks and Possible Side Effects of Spironolactone (Androgen Blocker):**

- Increased urine production and need to urinate (i.e., pee) more frequently, along with possible changes in kidney function.
- A drop in blood pressure and feeling lightheaded, especially when standing up from sitting or lying down.
- Increased thirst and/or dehydration.
- Increase in the potassium in the blood in your body; this can lead to muscle weakness, nerve problems and dangerous heart arrhythmias (irregular heart rhythm).
- If used without additional hormone therapy, androgen blockers may cause hot flashes and low mood or energy.
- Long-term use of androgen blockers to fully block testosterone without additional hormone therapy may result in bone loss.

## Risks and Benefits of Estrogen and Spironolactone

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### Expectations, Rights, and Responsibilities

- Take androgen blockers and/or estrogens only at the dosage and in the form prescribed. Taking medications in doses that are higher than recommended will increase any risks from these medications. There is no evidence to suggest that higher doses than generally recommended will work better or faster.
- You may choose to stop taking hormone therapy at any time or for any reason. Suddenly stopping estrogen after you have been on it for a long time may have negative physical and mental health effects. You are encouraged to discuss decisions with your medical provider prior to making any changes in your medication. It is best to make a plan for stopping the treatment with a medical provider familiar with hormone therapy.
- If you have or develop any condition you think may cause harm or worsen while taking hormone therapy, work with your medical provider to evaluate and create a plan to best manage that condition.
- Inform your medical provider if you are taking or plan to start taking other prescription drugs, dietary supplements, herbal or homeopathic drugs, street/recreational drugs, or alcohol. Being honest about what you are taking/using will help your medical provider prevent or reduce potentially harmful reactions or interactions.
- Inform your medical provider of any new physical symptoms and any medical conditions that may develop before or while you are taking hormone therapy.
- Inform your provider if you think you are having bad side effects from the medications.
- Your provider may recommend decreasing your dose or, on rare occasions, stopping estrogen and/or androgen blockers because of medical reasons and/or safety concerns. You can expect the medical provider to discuss all treatment decisions with you. Some people may also need to change, decrease, and/or stop hormone therapy as they age.
- If you want or need surgery in the future, surgeons may require that you stop taking estrogen for a few weeks before and after surgery. The surgeon will determine when this is necessary.
- Keep appointments for follow-up monitoring and other preventative health care needs, as recommended by your medical provider.
- Blood testing may be recommended to monitor your health and hormone treatment. Your medical provider will discuss with you what tests are necessary and any recommendations for ongoing care and monitoring.
- Hormone therapy is not the only way to affirm your gender. Your medical provider and/or a behavioral health provider are able to talk with you about other options if you are interested.