

		<p>Taking Spironolactone affects the balance of potassium in the kidneys, which may result in the minor experience high potassium levels resulting in:</p> <ul style="list-style-type: none"> • Changes in heart rhythms that may be life threatening • Low blood pressure, which can cause: <ul style="list-style-type: none"> ○ Fatigue ○ Lightheadedness ○ Tingling feelings ○ Muscle weakness ○ Shortness of breath • The minor's need for regular blood tests to monitor risks while on the medication
		<p>Taking Bicalutamide may cause numerous side effects which should be reported to the minor's prescribing physician, including:</p> <ul style="list-style-type: none"> • Hot flashes or flushing • Bone, back, or pelvic pain • Muscle weakness • Muscle or joint pain • Headaches • Shortness of breath • Chest pain • Elevated blood pressure • Swelling of the hands, feet, ankles, or lower legs • Cough • Constipation • Nausea • Vomiting • Abdominal pain • Diarrhea • Gas • Changes in weight (loss or gain) • Loss of appetite • Dizziness • Pain, burning, or tingling in the hands or feet • Difficulty sleeping • Feeling of uneasiness or dread • Rash • Sweating • Need to urinate frequently during the night

			<ul style="list-style-type: none"> • Bloody urine • Painful or difficult urination • Frequent and urgent need to urinate • Difficulty emptying bladder • Painful or swollen breasts • Yellowing of the skin or eyes • Pain in the upper right part of the abdomen • Extreme tiredness • Unusual bleeding or bruising • Lack of energy • Upset stomach • Loss of appetite • Flu-like symptoms • Dull or sharp side pain
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Requirements of Treatment with Feminizing Medications

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Compliance with the requirements explained above is a prerequisite for a minor to receive treatment with feminizing medications.
			The prescribing physician may stop prescribing feminizing medications if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
			The parent/guardian or the minor can change their mind and stop treatment at any time although some effects of HRT may be permanent.

Prevention of Complications while under Treatment with Feminizing Medications

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			The undersigned parent(s)/legal guardian(s) agree(s) to notify the minor's prescribing

			<p>physician if the minor suffers from any side effects during treatment or is unhappy with the treatment in any way, particularly if the parent(s)/legal guardian(s) has/have any concerns that the minor has worsening signs of depression or anxiety or expresses a desire harm themselves or attempt suicide.</p>
			<p>The prescribing physician is required to monitor the minor for any side effects during treatment and may refer the minor to another physician or specialist for treatment. The undersigned parent(s)/legal guardian(s) agree(s) to take the minor to physicians and specialists as recommended by the prescribing physician.</p>

PARENTAL CONSENT:

The signature(s) below confirm(s) the following:

1. The minor’s prescribing physician has fully informed me about:
 - a. the benefits and risks of taking feminizing medications;
 - b. the possible or likely consequences of hormone therapy; and
 - c. potential alternative treatments.
2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with feminizing medications. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.
3. I have had sufficient time and opportunity to discuss relevant treatment options with the minor’s prescribing physician.
4. All my questions have been answered to my satisfaction by the minor’s prescribing physician.
5. I know enough to give informed consent for the minor to take, refuse, or postpone taking feminizing medications.
6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.

7. My signature below attests to my consent for the minor to begin treatment with feminizing medications.

Parent/legal guardian's printed name (required)

Parent/legal guardian's signature (required)

Date

Parent/legal guardian's printed name (optional)

Parent/legal guardian's signature (optional)

Date

PRESCRIBING PHYSICIAN SIGNATURE:

My signature below attests to my compliance with section 456.52, Florida Statutes.

Prescribing physician's printed name (required)

Prescribing physician's signature (required)

Date

ASSENT OF A MINOR:

I have discussed the benefits and risks of treatment with feminizing medications with my prescribing physician, parent(s) or legal guardian(s), and I wish to receive them.

Minor's printed name (required)

Minor's signature (required)

Date

WITNESS:

Witness' printed name (required)

Witness' signature (required)

Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent and/or assent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient and/or adult(s) legally responsible for the minor child has indicated understanding of the contents of this form.

Interpreter's printed name

Interpreter's signature

Date

Masculinizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Parental Consent and Assent for Minors

Before a minor starts or continues treatment with hormones or hormone antagonists, you and the minor need to be aware of the effects and possible risks associated with use of these medications.

After your questions or concerns are addressed and you have decided to have the minor start or continue treatment with hormones or hormone antagonists, a parent/legal guardian and the minor must initial the statements below and sign this form. Both the parent/legal guardian and the minor must sign in person.

Medical treatment of children people with gender dysphoria is based on very limited, poor-quality research. Even the World Professional Association for Transgender Health acknowledges the limited science to support these treatments in children in their recently published Standards of Care version 8 (S45-46) where they state the following:

“A key challenge in adolescent transgender care is the quality of evidence evaluating the effectiveness of medically necessary gender-affirming medical and surgical treatments over time. Given the lifelong implications of medical treatment and the young age at which treatments may be started, adolescents, their parents, and care providers should be informed about the nature of the evidence base. It seems reasonable that decisions to move forward with medical and surgical treatments should be made carefully. Despite the slowly growing body of evidence supporting the effectiveness of early medical intervention, the number of studies is still low, and there are few outcome studies that follow youth into adulthood.”~~with only subtle improvements seen in some patient’s psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.~~

What are the medications that can masculinize one’s appearance?

Treatment with hormones is called hormone replacement therapy or HRT. HRT will require taking testosterone, which increases muscle mass and causes the development of facial hair and a deeper voice. Testosterone when used by minors, even when the criteria listed below are followed, does not have U.S. Food and Drug Administration (FDA) approval to be used by minors and its use in this population is considered “off label” because they are not being used for their intended purpose.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian	Parent/legal guardian	Minor (required)
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(required)	(optional)	

What are my other options if I do not wish to start or continue my minor’s treatment with hormones or hormone antagonists?

One option available is psychological therapy with a mental health care provider. This is recommended regardless of whether or not the minor undergoes treatment with hormones or hormone antagonists due to the high risk of anxiety, depression, self-harm, and suicide. Other options may be discussed with your prescribing physician.

How is testosterone taken?

Testosterone is usually injected every one to four weeks. Typically, it is not given in pill form because the body may not absorb it properly which may cause potentially fatal liver problems. The doses used for injection differ from product to product and from patient to patient. The injections are given in the muscle (intramuscular) or can be given with a smaller needle under the skin (subcutaneous). A minor taking testosterone may experience unwanted swings in hormone levels based on the amount and how often doses are given.

Every medication has risks, benefits, and side effects that are important to understand before taking. The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to the minor’s prescribing physician to make sure that there are no negative medical or mental health effects.

Both testosterone and the treatment process can affect a minor’s mood. Therefore, minors must be under the care of a licensed mental health care professional while undergoing treatment. This professional can work with the minor, your family and friends, and your school staff.

What are the requirements to receive hormone replacement therapy (HRT)?

To receive HRT, there are specific requirements that need to be met before and during treatment. These requirements will allow the prescribing physician to monitor the minor’s medical and mental health status during treatment. If these requirements are not met, HRT may be discontinued by the prescribing physician.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Before beginning or continuing HRT, a minor needs to undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist. The psychiatrist or psychologist must submit a letter to the prescribing physician confirming this.

The specific requirements for a minor to receive and continue HRT treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders (DSM) or International Classification of Diseases (ICD);
2. Has pubertal changes resulting in an increase in gender dysphoria;
3. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
4. Has psychological and social support during treatment;
5. Has experienced puberty to at least Tanner Stage 2 (first stage of puberty), which must be confirmed by a physician;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery;
7. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician at least every 6 months;
8. Undergoes a suicide risk assessment such as PHQ-9 by their physician by a licensed mental health care professional at least every 3 months; with positive screens sent to their Florida licensed psychologist or psychiatrist.
9. Undergoes relevant laboratory testing, at least every 3-64 months;
10. X-ray of the hand (bone age) at least once a year if the minor is still growing;
11. Annual bone density scan (DEXA) which will allow monitoring of the minor's bone density (bone strength) during treatment, which can be altered by HRT
12. Annual mental health assessments by a Board-certified Florida licensed psychiatrist or psychologist; and
13. Continued counseling is strongly encouraged with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Summary of Testosterone Benefits and Risks

BENEFITS	RISKS
<ul style="list-style-type: none"> • Appear more like a man • Bigger clitoris • Coarser skin • Lower voice • More body hair • More facial hair • More muscle mass • More strength • No or minimal menstrual periods • More physical energy • More sex drive 	<ul style="list-style-type: none"> • Acne (may permanently scar) • Blood clots (thrombophlebitis), risk significantly increased by smoking • Emotional changes, for example, more aggression • Headache • High blood pressure (hypertension) • Increased red-blood-cell count • Infertility • Inflamed liver • Interaction with drugs for diabetes and blood thinning such as Coumadin and Warfarin • Male pattern baldness • More abdominal fat – redistributed to a male shape • Risk of heart disease • Swelling of hands, feet, and legs • Weight gain

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Please initial each statement on this form to show that you understand the benefits, risks, and changes associated with a minor taking testosterone.

Masculinizing Effects

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Testosterone may be prescribed to make a minor appear less like a female and more like a male.
			It can take several months or longer for the effects of testosterone to become noticeable and no one can predict how fast or how much change will occur.
			Changes from testosterone may not be complete for 2 to 5 years after treatment is started.
			<p>The following changes are likely to be permanent even if testosterone is discontinued:</p> <ul style="list-style-type: none"> • Bigger clitoris - typically about half an inch to a little more than an inch • Deeper voice • Gradual growth of moustache and beard • Hair loss at the temples and crown of the head and the possibility of being completely bald • More, thicker, and coarser hair on abdomen, arms, back, chest, and legs
			<p>The following changes could be permanent, but may improve if I stop taking testosterone:</p> <ul style="list-style-type: none"> • Acne (although there may be permanent scars) • Menstrual periods (if present), typically stop one to six months after starting • More abdominal fat – redistributed to a male shape: decreased on buttocks, hips, and thighs; increased in abdomen – changing from “pear shape” to “apple shape” • More muscle mass and strength • More sexual interest • Vaginal dryness • Vaginal tearing • Vaginal bleeding • Vaginal pain • Vaginal infection • Painful intercourse

			This treatment will not change the minor’s biological sex or chromosomes.
			Testosterone may reduce the minor’s ability to become pregnant, but it will not eliminate the risk of pregnancy. A person can become pregnant while on testosterone. I agree to inform the minor’s prescribing physician if the minor becomes pregnant.
			Some aspects of the minor’s body will not change: <ul style="list-style-type: none"> • Fat loss may make breasts appear slightly smaller (if present) • The voice will deepen, but other aspects of the way the minor speaks may not sound more masculine
			Mood changes may be caused by these medicines, and the minor <u>should for safety reasons will</u> continue therapy with a licensed mental health care professional during treatment.
			Using these medicines to masculinize a minor is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of the minor’s prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of HRT for minors.

Risks of Testosterone

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Testosterone SHOULD NOT be used by anyone who: <ul style="list-style-type: none"> • Is pregnant • Has uncontrolled coronary artery disease as it could increase your risk for a fatal heart attack
			Testosterone should be used WITH CAUTION and only after a full discussion of risks by anyone who: <ul style="list-style-type: none"> • Has acne • Has a family history of heart disease or breast cancer • Has had a blood clot • Has high levels of cholesterol

			<ul style="list-style-type: none"> • Has liver disease • Has a high red blood cell count • Is obese • Smokes cigarettes or uses tobacco products
			The medical effects and the safety of minors taking testosterone are not completely known and there may be unknown long-term risks.
			Taking testosterone causes changes that other people will notice.
			Treatment with testosterone will not prevent serious psychiatric events, including suicide.
			<p>The minor must not take more testosterone than prescribed. Taking too much testosterone:</p> <ul style="list-style-type: none"> • Will increase health risks; • Will not make changes happen more quickly or more significantly; and • May cause the body to convert extra testosterone into estrogen that can slow down or stop the minor appearing more masculine
			<p>Taking testosterone can cause changes that increase the risk of heart disease into adulthood. These changes include:</p> <ul style="list-style-type: none"> • Less good cholesterol (HDL) that may protect against heart disease and more bad cholesterol (LDL) that may increase the risk of heart disease; • Higher blood pressure; and • More deposits of fat around the internal organs
			Taking testosterone can damage the liver and possibly lead to liver disease.
			Taking testosterone can increase red blood cells and hemoglobin, which may increase my risk of life-threatening problems such as stroke or heart attack.
			Taking testosterone can increase the risk for diabetes (high blood sugars), which decrease the body's response to insulin, cause weight gain, and increase deposits of fat around internal organs increasing the risk of heart disease and stroke.
			Treatment with testosterone can cause ovaries to not release eggs and may cause infertility.
			Treatment with testosterone increases the risk of cancer to the uterus, ovaries, or breasts. It is unclear if taking testosterone plays any role in HPV infection or cervical cancer.

			Taking testosterone causes or worsen migraines.
			Taking testosterone can cause emotional changes, such as irritability, frustration, aggression, and anger.

Requirements of Treatment with HRT

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Compliance with the requirements explained above is a prerequisite for a minor to receive treatment with testosterone.
			The prescribing physician may stop prescribing testosterone if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
			The parent/guardian or the minor can change their mind and stop treatment at any time although some effects of HRT may be permanent.

Prevention of Complications while under Treatment with HRT

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			The undersigned parent(s)/legal guardian(s) agree(s) to notify the minor's prescribing physician if the minor suffers from any side effects during treatment or is unhappy with the treatment in any way, particularly if the parent(s)/legal guardian(s) has/have any concerns that the minor has worsening signs of depression or anxiety or expresses a desire harm themselves or attempt suicide.
			The prescribing physician is required to monitor the minor for any side effects during treatment and may refer the minor to another physician or specialist for treatment. The undersigned parent(s)/legal guardian(s) agree(s) to take the minor physicians and specialists as recommended

by the prescribing physician.

PARENTAL CONSENT:

The signature(s) below confirm(s) the following:

1. The minor’s prescribing physician has fully informed me about:
 - a. the benefits and risks of taking testosterone;
 - b. the possible or likely consequences of hormone therapy; and
 - c. potential alternative treatments.

2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with testosterone. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with the minor’s prescribing physician.

4. All my questions have been answered to my satisfaction by the minor’s prescribing physician.

5. I know enough to give informed consent for the minor to take, refuse, or postpone taking testosterone.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.

7. My signature below attests to my consent for the minor to begin treatment with testosterone.

Parent/legal guardian’s printed name (required)

Parent/legal guardian’s signature (required)

Date

Parent/legal guardian's printed name (optional)

Parent/legal guardian's signature (optional)

Date

PRESCRIBING PHYSICIAN:

My signature below attests to my compliance with 456.52, Florida Statutes.

Prescribing physician's printed name (required)

Prescribing physician's signature (required)

Date

ASSENT OF A MINOR:

I have discussed the benefits and risks of treatment with masculinizing medication with my prescribing physician, parent(s) or legal guardian(s), and I wish to receive it.

Minor's printed name (required)

Minor's signature (required)

Date

WITNESS:

Witness' printed name (required)

Witness' signature (required)

Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent and/or assent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient and/or adult(s) legally responsible for the minor child has indicated understanding of the contents of this form.

Interpreter's printed name

Interpreter's signature

Date

Feminizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Consent

Before starting or continuing treatment with hormones or hormone antagonists, you need to be aware of the effects and possible risks associated with use of these medications.

Your prescribing physician will make a medical decision in consultation with you about the medications that are best for you, keeping in mind your overall health during the treatment process. Your prescribing physician will discuss with you all of the available information relating to hormone therapy. You are asked to read and understand the following information and to discuss any questions you have with your prescribing physician.

After your questions or concerns are addressed and you have decided to start or continue treatment with hormones or hormone antagonists, you must initial the statements below and sign this form in person with your prescribing physician.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research ~~with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies.~~ This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are the different medications that can feminize one's appearance?

Treatment with hormones is called hormone replacement therapy or HRT. HRT will require taking estrogen, as well as medicines to block the body from producing or utilizing testosterone. Use of these medications, even when the criteria listed below are followed, does not have U.S. Food and Drug Administration (FDA) approval and its use to treat gender dysphoria is considered "off label" because they are not being used for their intended purpose

Different forms of estrogen are used to feminize a person's appearance. Estrogen can be given as an injection either weekly or every other week, as a pill that is taken daily or twice a day, or as a patch that is changed weekly or every three or four days.

Please initial below to acknowledge your understanding of the information on this page.

Patient

Medications that block the production or effects of testosterone are called androgen blockers. Spironolactone is the androgen blocker that is most commonly used in the United States. In some cases, Bicalutamide, an antiandrogen, is used to block the effects of testosterone, though it will not reduce testosterone levels. Bicalutamide (brand name Casodex) is a cancer drug approved for the treatment of prostate cancer. Fulminant hepatotoxicity, a severe liver injury often resulting in death, has been noted with bicalutamide use.

Cyproterone acetate, a synthetic progestogen with strong antiandrogen activity, is commonly used in many countries but not in the USA. When paired with estrogen, cyproterone acetate is associated with elevated prolactin, decreased HDL cholesterol, and rare meningiomas (tumors). Cyproterone acetate has also been associated with uncommon episodes of fulminant hepatitis.

The administration of finasteride blocks the conversion of testosterone to the more potent androgen dihydrotestosterone. The FDA approved uses of finasteride include the treatment benign prostatic hypertrophy and androgenic alopecia. Finasteride is not recommended for routine use in treating populations with gender dysphoria.

Various forms of progestins may also be used. This class includes micronized bioidentical progesterone (Prometrium) as well as oral medroxyprogesterone acetate (Provera). Although there are anecdotal reports of progesterone use for breast development and mood management, there is currently insufficient evidence that the potential benefits of progesterone administration outweigh the potential risks. There is also a theoretical risk of breast cancer associated with long-term exogenous progesterone.

Every medication has risks, benefits, and side effects that are important to understand before taking. The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to your prescribing physician to make sure that there are no negative medical or mental health effects.

HRT, the use of androgen blockers and antiandrogens, and the treatment process can affect your mood. Therefore, you must be under the care of a licensed mental health care professional while undergoing treatment.

Please initial below to acknowledge your understanding of the information on this page.

Patient

What are my other options if I do not wish to start or continue treatment with hormones, hormone antagonists, or antiandrogens?

One option available is psychological therapy with a mental health provider. This is recommended regardless of whether or not the person undergoes treatment with hormones, hormone antagonists, or antiandrogens due to the high risk of anxiety, depression, self-harm, and suicide. Other options may be discussed with your prescribing physician.

What are the requirements to receive hormone replacement therapy (HRT)?

To receive HRT, there are specific requirements that need to be met before and during treatment. These requirements will allow the prescribing physician to monitor your medical and mental health status during treatment. If these requirements are not met, HRT may be discontinued by the prescribing physician.

Please initial below to acknowledge your understanding of the information on this page.

Patient

The specific requirements for you to receive and continue HRT treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders or International Classification of Diseases;
2. Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
3. Demonstrates capacity to consent for the specific gender dysphoria hormone treatment;
4. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
5. Has psychological and social support during treatment;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery; and
7. Understands the effect of hormone treatment on reproduction and they have explored reproductive options;

The following may also be recommended by your prescribing physician:

1. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician every 3 months for the initial year and at least annually thereafter;
2. Undergoes a suicide risk assessment such as PHQ-9 by their physician a licensed mental health care professional at least every 3 months for the initial year and at least annually thereafter; patients who have a positive screening, should be referred to a Florida licensed psychiatrist or psychologist.
3. Undergoes relevant laboratory testing at least every 6 months;
4. Annual bone density scan (DEXA) once a year for the first 5 years to allow monitoring of your bone density (bone strength) during treatment, which can be altered by HRT;
5. Annual mental health assessments by a board-certified Florida licensed psychiatrist or psychologist; and
6. Continued counseling is strongly encouraged with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Please initial below to acknowledge your understanding of the information on this page.

Patient

Please initial each statement on this form to show that you understand the benefits, risks, and changes associated with taking feminizing medications.

Effects of Feminizing Medications

Patient	Statement
	Feminizing medications, including estrogen, androgen blockers, or antiandrogens, given singularly or in combination, may be prescribed to make me appear less like a male and more like a female.
	It can take several months or longer for the effects of feminizing medications to become noticeable and no one can predict how fast or how much change will occur.
	This treatment will not change my biological sex or chromosomes.
	<p>If I take estrogen, the following changes in my breasts will occur:</p> <ul style="list-style-type: none"> • Breasts will develop but will not reach their full size for several years • Breasts will remain even if estrogen treatment is discontinued • A milky discharge from the nipples may appear, which should be reported to my prescribing physician • My risk of breast cancer may significantly increase
	<p>If I take feminizing medications, my body will make less testosterone, which may affect my sex life in different ways, including:</p> <ul style="list-style-type: none"> • My testicles may shrink • My penis may never fully develop, particularly if I previously took puberty blockers • I will have fewer spontaneous erections • My sperm may no longer mature causing infertility which may be permanent even if treatment is discontinued, the risk of which is increased if I took puberty blockers prior to starting feminizing medications • Conversely, it is possible that my sperm could still mature while taking feminizing medications and I may cause someone to get pregnant
	The options for sperm banking have been explained.
	<p>If I take feminizing medications, some parts of my body will not change much, including:</p> <ul style="list-style-type: none"> • If present, my facial hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If present, my body hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If I went through puberty and have a deep voice, the pitch of my voice will not rise and my speech patterns will not become more like a woman's • If present, my Adam's apple will not shrink

	<p>Even if I stop taking feminizing medications, the following changes may occur:</p> <ul style="list-style-type: none"> • My body fat may be redistributed with less fat on the abdomen and more on the buttocks, hips, and thighs creating a more female shape • I may have decreased muscle mass and strength in the upper body • My skin may become softer
	<p>Mood changes may be caused by these medicines, and I will continue therapy with a licensed mental health care professional during treatment.</p>
	<p>Using these medicines to feminize my body is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based <u>on mostly low quality science, as well as solely on</u> the judgment and experience of my prescribing physician. There there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of feminizing medications.</p>

Risks of Feminizing Medications

Patient	Statement
	The medical effects and the safety of taking feminizing medications are not completely known and there may be unknown long-term risks.
	Taking feminizing medications causes changes that other people will notice.
	Treatment with feminizing medications will not prevent serious psychiatric events, including suicide.
	<p>I must not take more feminizing medication than prescribed. Taking too much medication:</p> <ul style="list-style-type: none"> • Will increase health risks • Will not make changes happen more quickly or more significantly
	Taking feminizing medication can damage the liver and possibly lead to liver disease.

Risks of Estrogen

Patient	Statement
	<p>Estrogen SHOULD NOT be used by anyone who has:</p> <ul style="list-style-type: none"> • Any estrogen-dependent cancer • Any disorder that makes them more likely to get blood clots that could travel to the lungs unless they are also taking blood thinners and are being followed by a specialist
	<p>Estrogen should be used WITH CAUTION and only after a full discussion of risks by anyone who:</p> <ul style="list-style-type: none"> • Has a family history of breast cancer or other cancers that grow more quickly when estrogens are present

	<ul style="list-style-type: none"> • Has a family history of heart disease • Has diabetes • Has chronic hepatitis or other liver disease • Has high levels of cholesterol • Has migraines or seizures • Is obese • Smokes cigarettes or uses tobacco products
	<p>Taking estrogen increases the risk of blood clots and problems with blood vessels that can result in:</p> <ul style="list-style-type: none"> • Chronic problems with veins in the legs, which may require surgery • Heart attack which may cause permanent heart damage or death • Pulmonary embolism (blood clot in the lungs), which may cause permanent lung damage or death • Stroke, which may cause permanent brain damage or death
	<p>The risk of blood clots while take estrogen is much greater if you smoke cigarettes. The danger is so high that you should stop smoking completely while taking estrogen.</p>
	<p>Taking estrogen can increase the deposits of fat around internal organs, which increases the risk for diabetes and heart disease, which in turn increases the risk of heart attack and stroke.</p>
	<p>Taking estrogen can raise blood pressure, which increases the risk of heart attack and stroke.</p>
	<p>Taking estrogen increases the risk of gallstones (stones in the gallbladder). Any long-term abdominal pain you experience while taking estrogen must be reported to your prescribing physician.</p>
	<p>Taking estrogen increases the risk of elevated prolactin levels and prolactinomas, which are non-cancerous tumors of the pituitary gland. While not typically life threatening, prolactinomas can damage your vision and cause headaches if not treated properly. Any changes in your vision, the occurrence of headaches that are worse when waking up in the morning, or any milky discharge from the nipples must be reported to your prescribing physician.</p>
	<p>Taking estrogen can cause nausea and vomiting. Any long-term nausea or vomiting must be reported to your prescribing physician.</p>
	<p>Taking estrogen can cause migraines or can make them worse if you already have them.</p>
	<p>Taking estrogen can cause hot flashes.</p>
	<p>Taking estrogen can cause you to feel tired and have difficulty focusing.</p>

Risks of Androgen Blockers and Antiandrogens (Spironolactone and Bicalutamide)

Patient	Statement
	<p>Taking Spironolactone affects the balance of water and salt in the kidneys, which may:</p> <ul style="list-style-type: none"> • Increase the amount of urine produced by your kidneys, making it necessary to urinate more frequently • Increase your thirst • Increase your risk of dehydration, which can be evidenced by less frequent urination than usual, dark and strong-smelling urine, thirst, and light-headedness
	<p>Taking Spironolactone affects the balance of potassium in the kidneys, which may result in you experiencing high potassium levels resulting in:</p> <ul style="list-style-type: none"> • Changes in heart rhythms that may be life threatening • Low blood pressure, which can cause: <ul style="list-style-type: none"> ○ Fatigue ○ Lightheadedness ○ Tingling feelings ○ Muscle weakness ○ Shortness of breath • Your need for regular blood tests to monitor risks while on the medication
	<p>Taking Bicalutamide may cause numerous side effects which should be reported to your prescribing physician, including:</p> <ul style="list-style-type: none"> • Hot flashes or flushing • Bone, back, or pelvic pain • Muscle weakness • Muscle or joint pain • Headaches • Shortness of breath • Chest pain • Elevated blood pressure • Swelling of the hands, feet, ankles, or lower legs • Cough • Constipation • Nausea • Vomiting • Abdominal pain • Diarrhea • Gas • Changes in weight (loss or gain) • Loss of appetite

	<ul style="list-style-type: none"> • Dizziness • Pain, burning, or tingling in the hands or feet • Difficulty sleeping • Feeling of uneasiness or dread • Rash • Sweating • Need to urinate frequently during the night • Bloody urine • Painful or difficult urination • Frequent and urgent need to urinate • Difficulty emptying bladder • Painful or swollen breasts • Yellowing of the skin or eyes • Pain in the upper right part of the abdomen • Extreme tiredness • Unusual bleeding or bruising • Lack of energy • Upset stomach • Loss of appetite • Flu-like symptoms • Dull or sharp side pain
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Requirements of Treatment with Feminizing Medications

Patient	Statement
	Compliance with the requirements explained above is a prerequisite for you to receive treatment with feminizing medications.
	The prescribing physician may stop prescribing feminizing medications if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
	I can change my mind and stop treatment at any time.

Prevention of Complications while under Treatment with Feminizing Medications

Patient	Statement
	I agree to notify the prescribing physician if I suffer from any side effects during treatment or are unhappy with the treatment in any way, particularly if I have any concerns about worsening signs of depression or anxiety or if I desire to harm myself or attempt suicide.

	<p>I acknowledge that taking feminizing medications is only a part of my overall health, and that a range of preventative health activities are necessary so that remain healthy. These include, but are not limited to:</p> <ul style="list-style-type: none"> • Monthly breast self-examination (report any new lumps to the prescribing physician) • Regular age-appropriate breast mammograms • Regular age-appropriate prostate examinations • Appropriate immunizations • Regular STI screening depending on my level of risk • HIV prevention depending on my level of risk • Regular physical activity, including resistance exercise for bone health • Healthy eating • Quitting smoking
	<p>The prescribing physician is required to monitor me for any side effects during treatment and may refer me to another physician or specialist for treatment. I agree to go to any physicians and specialists recommended by the prescribing physician.</p>

CONSENT:

The signature below confirms the following:

1. The prescribing physician has fully informed me about:
 - a. the benefits and risks of taking feminizing medications;
 - b. the possible or likely consequences of hormone therapy; and
 - c. potential alternative treatments.
2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with feminizing medications. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.
3. I have had sufficient time and opportunity to discuss relevant treatment options with the prescribing physician.
4. All my questions have been answered to my satisfaction by the prescribing physician.
5. I know enough to give informed consent for me to take, refuse, or postpone taking feminizing medications.
6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.
7. My signature below attests to my consent to begin treatment with feminizing medications.

Patient's printed name (required)

Patient's signature (required)

Date

PRESCRIBING PHYSICIAN SIGNATURE:

My signature below attests to my compliance with section 456.52, Florida Statutes.

Prescribing physician's printed name (required)

Prescribing physician's signature (required)

Date

WITNESS:

Witness' printed name (required)

Witness' signature (required)

Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient has indicated understanding of the contents of this form.

Interpreter's printed name

Interpreter's signature

Date

Masculinizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Consent

Before starting or continuing treatment with hormones or hormone antagonists, you need to be aware of the effects and possible risks associated with the use of these medications.

The prescribing physician will make a medical decision, in consultation with you, about the medications that are best for you, keeping in mind your overall health during your gender transition process. The effects and possible risks associated with the use of these medications will be discussed with you. It your responsibility to read and understand the following information and raise any questions you have with your prescribing physician.

After your questions or concerns are addressed and you have decided to start or continue hormones or hormone antagonists, you will need to initial the statements below and sign this form.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research. ~~with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies.~~ This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are the medications that can masculinize one's appearance?

Treatment with hormones is called hormone replacement therapy or HRT. HRT will require taking testosterone, which increases muscle mass and causes the development of facial hair and a deeper voice. Testosterone when used by biological women, even when the criteria listed below are followed, does not have the U.S. Food and Drug Administration (FDA) approval to be used in the treatment of gender dysphoria and is considered "off label" use because they are not being used for their intended purpose.

Please initial below to acknowledge your understanding of the information on this page.

Patient

How is testosterone taken?

Testosterone is usually injected every one to four weeks. Typically, it is not used as a pill because the body may not absorb it properly and may cause potentially fatal liver problems. The doses used for injection differ from product to product and from patient to patient. The injections are given in the muscle (intramuscular) or can be given with a smaller needle under the skin (subcutaneous). Taking testosterone may cause unwanted swings in hormone levels based on the amount and how often doses are given. Skin creams and patches may also be used. Both testosterone and the treatment process can affect mood. Therefore, individuals must be under the care of a licensed mental health care professional while undergoing treatment.

Finasteride is a treatment option for individuals experiencing bothersome alopecia resulting from higher dihydrotestosterone levels. The administration of 5 α -reductase inhibitors block the conversion of testosterone to the more potent androgen dihydrotestosterone. The FDA approved indications of finasteride administration include benign prostatic hypertrophy and androgenetic alopecia. The use of 5 α -reductase inhibitors may impair clitoral growth and the development of facial and body hair. Future studies are needed to assess the efficacy and safety of 5 α -reductase inhibitors in treatment for gender dysphoria.

Every medication has risks, benefits, and side effects that are important to understand before taking. The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to the prescribing physician to make sure that there are no negative medical or mental health effects.

What are my other options if I do not wish to start or continue medical treatments?

One option available is psychological therapy with a mental health care provider. This is recommended regardless of whether the individual undergoes treatment with hormones or hormone antagonists or not, due to the high risk of anxiety, depression, self-harm, and suicide. Other options may be discussed with your prescribing physician.

Please initial below to acknowledge your understanding of the information on this page.

Patient

What are the requirements to receive hormone replacement therapy?

To receive hormone replacement therapy, there are specific requirements that need to be met before and during the treatment. These requirements will allow the prescribing physician to monitor medical as well as mental health wellbeing during HRT. If these requirements are not met, HRT may be discontinued by the prescribing physician.

The specific requirements for an individual to receive and continue HRT treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders (DSM) or International Classification of Diseases (ICD);
2. Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
3. Demonstrates capacity to consent for the specific gender dysphoria hormone treatment;
4. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
5. Has psychological and social support during treatment;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery; and
7. Understands the effect of hormone treatment on reproduction and they have explored reproductive options.

Please initial below to acknowledge your understanding of the information on this page.

Patient

The following may also be recommended by your prescribing physician:

1. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician every 3 months for the initial year and at least annually thereafter;
2. Undergoes a suicide risk assessment such as PHQ-9 by your physician a licensed mental health care professional at least every 3 months for the initial year and at least annually thereafter; positive screens will be sent to your Florida licensed psychologist or psychiatrist.
3. Undergoes relevant laboratory testing, at least every 6 months;
4. Annual bone scan (DEXA) once a year for the first 5 years to allow monitoring of bone density (bone strength) during treatment, which can be altered by poor compliance with HRT;
5. Annual mental health assessments by a board-certified Florida licensed psychiatrist or psychologist; and
6. Continued counseling is strongly encouraged with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Summary of Testosterone Benefits and Risk

BENEFITS	RISKS
<ul style="list-style-type: none"> • Appear more like a man • Bigger clitoris • Coarser skin • Lower voice • More body hair • More facial hair • More muscle mass • More strength • No or minimal menstrual periods • More physical energy • More sex drive 	<ul style="list-style-type: none"> • Acne (may permanently scar) • Blood clots (thrombophlebitis), risk significantly increased by smoking • Emotional changes, for example, more aggression • Headache • High blood pressure (hypertension) • Increased red-blood-cell count • Infertility • Inflamed liver • Interaction with drugs for diabetes and blood thinning — for example Coumadin and Warfarin • Male pattern baldness • More abdominal fat — redistributed to a male shape • Risk of heart disease • Swelling of hands, feet, and legs • Weight gain

Please initial below to acknowledge your understanding of the information on this page.

Patient

Please initial each statement on this form to show that you understand the benefits, risks, and changes that may occur from taking testosterone.

Masculinizing Effects

Patient	Statement
	Testosterone may be prescribed to make me appear less like a female and more like a male.
	It can take several months or longer for the effects of testosterone to become noticeable and no one can predict how fast or how much change will occur.
	<p>The following changes are likely to be permanent even if testosterone is discontinued:</p> <ul style="list-style-type: none"> • Bigger clitoris - typically about half an inch to a little more than an inch • Deeper voice • Gradual growth of moustache and beard • Hair loss at the temples and crown of the head and the possibility of being completely bald • More, thicker, and coarser hair on abdomen, arms, back, chest, and legs
	<p>The following changes could be permanent, but may improve if I stop taking testosterone:</p> <ul style="list-style-type: none"> • Acne (although there may be permanent scars) • Menstrual periods (if present), typically stop one to six months after starting • More abdominal fat – redistributed to a male shape: decreased on buttocks, hips, and thighs; increased in abdomen – changing from “pear shape” to “apple shape” • More muscle mass and strength • More sexual interest • Vaginal dryness • Vaginal Tearing • Vaginal Bleeding • Vaginal Pain • Vaginal infection • Painful intercourse
	This treatment will not change the individual’ s biological sex or chromosomes.

	Testosterone may reduce the ability to become pregnant, but it will not eliminate the risk of pregnancy. A person may become pregnant while on testosterone. I agree to inform the prescribing physician if I become pregnant.
	Some aspects of my body will not change: <ul style="list-style-type: none"> • Fat loss may make breasts appear slightly smaller • The voice will deepen, but other aspects of the way I speak may not sound more masculine
	Mood changes may be caused by these medicines, and I will continue therapy with a licensed mental health care professional during treatment.
	Using these medicines to masculinize is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of the prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of HRT.

Risks of Testosterone

Patient	Statement
	Testosterone SHOULD NOT be used by anyone who: <ul style="list-style-type: none"> • Is pregnant • Has uncontrolled coronary artery disease as it could increase your risk for a fatal heart attack
	It should be used WITH CAUTION and only after a full discussion of risks by anyone who: <ul style="list-style-type: none"> • Has acne • Has a family history of heart disease or breast cancer • Has had a blood clot • Has high levels of cholesterol • Has liver disease • Has a high red blood cell count • Is obese • Smokes cigarettes
	The medical effects and the safety of testosterone are not completely known and there may be unknown long-term risks.
	Taking testosterone causes changes that other people will notice.
	Treatment with testosterone will not prevent serious psychiatric events, including suicide.
	Taking more testosterone than prescribed: <ul style="list-style-type: none"> • Will increase health risks; • Will not make changes happen more quickly or more significantly; and

	<ul style="list-style-type: none"> • May cause the body to convert extra testosterone into estrogen that can slow down or stop me from appearing more masculine.
	<p>Taking testosterone can cause changes that increase the risk of heart disease. These changes include:</p> <ul style="list-style-type: none"> • Less good cholesterol (HDL) that may protect against heart disease and more bad cholesterol (LDL) that may increase the risk of heart disease; • Higher blood pressure; and • More deposits of fat around the internal organs
	Taking testosterone can damage the liver and possibly lead to liver disease.
	Taking testosterone can increase red blood cells and hemoglobin, which may increase my risk of life-threatening problems such as stroke or heart attack.
	Taking testosterone can increase the risk for diabetes (high blood sugars), which decrease the body's response to insulin, cause weight gain, and increase deposits of fat around internal organs increasing the risk of heart disease and stroke.
	Treatment with testosterone can cause ovaries to not release eggs and may cause infertility.
	Treatment with testosterone increases the risk of cancer to the uterus, ovaries, or breasts. It is unclear if taking testosterone plays any role in HPV infection or cervical cancer.
	Taking testosterone causes or worsens migraines.
	Taking testosterone can cause emotional changes, such as irritability, frustration, aggression, and anger.

Risks of Finasteride

Patient	Statement[®]
	Finasteride may be an appropriate treatment option in individuals experiencing bothersome alopecia resulting from testosterone treatment.
	<p>Finasteride may have side effects which include:</p> <ul style="list-style-type: none"> • decreased libido • dry skin • acne • Breast swelling and tenderness • headache • irregular menstruation • dizziness • increased body hair
	Finasteride is not approved by the FDA for use in biological women and is forbidden in pregnant women due to birth defects.

Requirements of Treatment with HRT

Patient	Statement
	Compliance with the requirements explained above is a prerequisite to receive treatment with testosterone.
	The prescribing physician may stop prescribing testosterone if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
	I understand that I may decide to stop treatment at any time.

Prevention of Complications while under Treatment of HRT

Patient	Statement
	I agree to notify the prescribing physician if I suffer from any side effects during treatment or am unhappy with the treatment in any way, and if I have any concerns that I have worsening signs of depression or anxiety or wants to harm myself or attempt suicide or attempt suicide.
	The prescribing physician is required to monitor me for any side effects during treatment and may refer me to another physician or specialist for treatment.

CONSENT:**My signature below confirms that:**

1. My prescribing physician has talked with me about:
 - a. the benefits and risks of taking testosterone;
 - b. the possible or likely consequences of hormone therapy; and
 - c. potential alternative treatments.
2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with testosterone. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.
3. I have had sufficient time and opportunity to discuss relevant treatment options with my prescribing physician.
4. All my questions have been answered to my satisfaction by my prescribing physician.
5. I know enough to give informed consent to take, refuse, or postpone taking testosterone.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.

7. My signature below attests to my consent to begin treatment with testosterone.

Based on all this information:

- _____ I want to begin or continue taking testosterone
- _____ I want to begin or continue taking finasteride
- _____ I do not wish to begin or continue taking masculinizing medication

Patient's printed name (required)

Patient's signature (required)

Date

PRESCRIBING PHYSICIAN:

My signature below attests to my compliance with 456.52, Florida Statutes.

Prescribing physician's printed name (required)

Prescribing physician's signature (required)

Date

WITNESS:

Witness' printed name (required)

Witness' signature (required)

Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent and/or assent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient has indicated understanding of the contents of this form.

Interpreter's printed name

Interpreter's signature

Date