Who should not take testosterone?

Testosterone **SHOULD NOT** be used by anyone who:

- 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:

- 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 or uses tobacco products

Summary of Testosterone Benefits and Risks

BENEFITS	RISKS
• 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	• 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 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	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.
			The following changes are likely to be permanent even if testosterone is discontinued: • 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
			The following changes could be permanent, but may improve if I stop taking testosterone: • 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
			This treatment will not change the minor's sex 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: • 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 will 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	Statement
			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.

			The minor must not take more testosterone than prescribed. Taking too much testosterone: • 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
			Taking testosterone can cause changes that increase the risk of heart disease into adulthood. These changes include: • 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	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	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.

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 fluid 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

DRAFT FOR JUNE 23, 2023 - JOINT COMMITTEE MEETING

64B8ER-XX/64B15ER-XX - Sex-reassignment Standards of Practice in Minors

The standards of practice in this rule do not supersede the level of care, skill, and treatment recognized in general law related to healthcare licensure.

(1) Pursuant to Section 456.52, Florida Statutes, sex-reassignment prescriptions and procedures are prohibited for patients younger than 18 years of age, except that a physician may continue to treat such patient with a prescription if such treatment for sex-reassignment was commenced before, and is still active on, May 17, 2023. The physician is required to obtain voluntary, informed consent while physically present in the same room as the patient. Consent is not required for renewal of such prescriptions if a physician and his or her patient have met the requirements for consent for the initial prescription or renewal; however, a separate consent is required for any new prescription for a pharmaceutical product not previously prescribed to the patient.

(2) Informed Consent. The Board has approved the following mandatory informed consent forms for the continued treatment of minors with sex-reassignment prescriptions:

(a) For patients prescribed puberty blocking medications, form DOH-MQA-XXXX, (06/23), entitled "NAME," which is hereby incorporated by reference and available from http://www.flrules.org/Gateway/reference.asp?No=Ref- and from the Board's website at [DOH LINK].

(b) For patients prescribed sex-reassignment feminizing medications, form DOH-MQA-XXXX, (06/23), entitled "NAME," which is hereby incorporated by reference and available from http://www.flrules.org/Gateway/reference.asp?No=Ref- and from the Board's website at [DOH LINK].

(c) For patients prescribed sex-reassignment masculinizing medications, form DOH-MQA-XXXX, (06/23), entitled "NAME," which is hereby incorporated by reference and available from http://www.flrules.org/Gateway/reference.asp?No=Ref- and from the Board's website at [DOH LINK].

(3) A Board-approved informed consent form is not executed until:

(a) The physician issuing the prescription, while physically present in the same room as the patient, has informed the patient and the patient's parent or legal guardian of the nature and risks of the prescription, and has provided and received the written acknowledgement of the patient and the patient's legal guardian before the prescription is prescribed or administered. The physician is prohibited from delegating this responsibility to another person. The physician is also required to sign the informed consent form.

(b) The patient's parent or legal guardian is required to sign the informed consent form.

(c) The patient is required to assent to the informed consent form.

(d) A competent witness is also required to sign the informed consent form.

(4) Standards of Practice. The nature and extent of the requirements set forth below will vary depending on the practice setting and circumstances presented to the prescribing physician. A prescribing physician who continues to treat a minor patient with sex-reassignment prescriptions pursuant to section 456.52(1)(a), Florida Statutes, shall comply with the following:

Clinical determinations.

(a) Patient Evaluation. An in-person thorough medical history and physical examination of the patient conducted by the prescribing physician must be documented in the patient's medical record prior to prescribing any new sex-reassignment prescription.

(b) Clinical determinations. Based on the patient evaluation, the following must be confirmed:

1. The patient meets the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders (DSM) or International Classification of Diseases (ICD);
2. The patient has pubertal changes resulting in an increase in gender dysphoria;
3. The patient does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
4. The patient will have adequate psychological and social support during treatment;
5. The patient has experienced puberty to at least Tanner Stage 2; and
6. The patient demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of puberty suppression, future cross-sex hormone treatment, as well as the medical and social risks and benefits of sex reassignment surgery based on the patient's current treatment status;

(c) Patient Visit. The physician must meet with the patient every three (3) months for the purpose of monitoring the patient and must document each visit in the patient's medical records.

(d) Suicide Risk Assessment. A suicide risk assessment by a licensed mental health care professional must be performed every three (3) months.

(e) Laboratory Testing. Relevant laboratory testing must be performed every four (4) months.

(f) X-rays. X-rays of the hand must be performed each year to monitor and document the patient's bone age progression.

(g) Bone (DEXA) Scan. A bone (DEXA) scan must be performed each year to monitor the patient's bone density during treatment.

(h) Mental Health Assessment. The physician must have the patient undergo a annual mental health assessment to be performed by a board-certified Florida licensed psychiatrist or psychologist.

(i) Counseling. The physician must refer the patient for counseling with a licensed mental health care professional during the treatment period, with a frequency as recommended by the licensed mental health care professional.

(j) Additional Consultations. The physician must refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives.

Rulemaking Authority 456.52 FS. Law Implemented 456.52 FS. History – New____.

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.

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.

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. 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.

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 that has experience in treating people with gender dysphoria. 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. Another option is _____.

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.

Before beginning or continuing HRT, you must 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 you to receive and continue HRT treatment include the following:

1. Meets 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. Gender dysphoria is marked and sustained;
4. Demonstrates capacity to consent for the specific gender dysphoria hormone treatment;
5. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
6. Has adequate psychological and social support during treatment;
7. 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;
8. Understands the effect of gender-affirming hormone treatment on reproduction and they have explored reproductive options;
9. Undergoes an evaluation by the prescribing physician at least every 3 months
10. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months;
11. Undergoes relevant laboratory testing at least every 6 months;
12. Bone (DEXA) scan once a year to allow monitoring of your bone density (bone strength) during treatment, which can be altered by HRT;
13. Annual mental health assessments by a board-certified Florida licensed psychiatrist or psychologist; and
14. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

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 sex chromosomes.

	If I take estrogen, the following changes in my breasts will occur: • 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
	If I take feminizing medications, my body will make less testosterone, which may affect my sex life in different ways, including: • 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.
	If I take feminizing medications, some parts of my body will not change much, including: • 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
	Even if I stop taking feminizing medications, the following changes may occur: • 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
	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 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 solely on the judgment and experience of my 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 feminizing medications.

Risks of Feminizing Medications

Patient	Statement
	The medical effects and the safety of taking femininizing medications are not completely known and there may be unknown long-term risks.
	Taking femininizing medications causes changes that other people will notice.
	Treatment with femininizing medications will not prevent serious psychiatric events, including suicide.
	I must not take more feminizing medication than prescribed. Taking too much medication: • 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

Estrogen **SHOULD NOT** be used by anyone who has:

- 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

Estrogen should be used **WITH CAUTION** and only after a full discussion of risks by anyone who:

- Has a family history of breast cancer or other cancers that grow more quickly when estrogens are present
- 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

Patient	Statement
	Taking estrogen increases the risk of blood clots and problems with blood vessels that can result in: • 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

	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.
	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.
	Taking estrogen can raise blood pressure, which increases the risk of heart attack and stroke.
	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.
	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.
	Taking estrogen can cause nausea and vomiting. Any long-term nausea or vomiting must be reported to your prescribing physician.
	Taking estrogen can cause migraines or can make them worse if you already have them.
	Taking estrogen can cause hot flashes.
	Taking estrogen can cause you to feel tired and have difficulty focusing.

Risks of Androgen Blockers and Antiandrogens (Spironolactone and Bicalutamide)

Patient	Statement
	Taking Spironolactone affects the balance of water and salt in the kidneys, which may: • 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

	Taking Spironolactone affects the balance of potassium in the kidneys, which may result in you experiencing high potassium levels resulting in:
	• Changes in heart rhythms that may be life threatening
	• Low blood pressure, which can cause:
	  ○ Fatigue
	  ○ Lightheadedness
	  ○ Tingling feelings
	  ○ Muscle weakness
	  ○ Shortness of breath

	• Your need for regular blood tests to monitor risks while on the medication
	Taking Bicalutamide may cause numerous side effects which should be reported to your prescribing physician, including: • 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 • 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

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.
	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: • 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
	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.

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.

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 fluid 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

Testosterone Treatment 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.

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.

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 5α-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 5α-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 5α-reductase inhibitors in 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 that has experience in treating people with gender dysphoria. 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. Another option is _____.

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.

Before beginning or continuing HRT, the individual 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 an individual to receive and continue HRT treatment include the following:

1. Meets 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. Gender dysphoria is marked and sustained;
4. Demonstrates capacity to consent for the specific gender dysphoria hormone treatment;
5. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
6. Has adequate psychological and social support during treatment;
7. 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;
8. Understands the effect of gender-affirming hormone treatment on reproduction and they have explored reproductive options;
9. Undergoes an evaluation by the prescribing physician at least every 3 months
10. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months;

11. Undergoes relevant laboratory testing, at least every 6 months;
12. Bone (DEXA) scan once a year to allow monitoring of bone density (bone strength) during treatment, which can be altered by HRT;
13. Annual mental health assessments by a board-certified Florida licensed psychiatrist or psychologist; and
14. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Who should not take testosterone?

Testosterone **SHOULD NOT** be used by anyone who:

- 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:

- 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

Summary of Testosterone Benefits and Risk

BENEFITS	RISKS
• 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	• 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 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.
	The following changes are likely to be permanent even if testosterone is discontinued: • 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
	The following changes could be permanent, but may improve if I stop taking testosterone: • 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
	This treatment will not change the individual' s sex chromosomes.
	Testosterone may reduce the ability to become pregnant, but it will not eliminate the risk of pregnancy. A person become pregnant while on testosterone. I agree to inform the prescribing physician if I become pregnant.
	Some aspects of my body will not change: • 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
	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 could may: • 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 me from appearing more masculine.
	Taking testosterone can cause changes that increase the risk of heart disease. These changes include: • 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.

Risks of Finasteride

Patient	Statement
	Finasteride may be an appropriate treatment option in individuals experiencing bothersome alopecia resulting from testosterone treatment.
	Finasteride may have side effects which include: • 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.

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 fluid 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

Surgical Treatment for Adults with Gender Dysphoria

Patient Information and Informed Consent

Before having surgery to treat gender dysphoria, you need to be aware of the effects and possible risks of these procedures. Your surgeon will make a medical decision, in consultation with you, about the procedures that are best for you, keeping in mind your overall health.

Your surgeon will discuss with you all the information relating to the surgery. You are asked to read and understand the following information and to discuss any questions you have with your surgeon. After your questions or concerns are addressed and you have decided to have surgery you must initial the statements below and sign this form in person with your surgeon.

What are the types of surgery to treat gender dysphoria?

Surgery to treat gender dysphoria may involve procedures on the face, chest, or genitalia. Common surgery options include:

- **Facial reconstructive surgery** to make facial features more masculine or feminine.
- **Chest or "Top" surgery** to remove breast tissue for a more masculine appearance or enhance breast size and shape for a more feminine appearance.
- **Genital or "Bottom" surgery** to transform and reconstruct the genitalia.
  - **Orchiectomy:** A bilateral orchiectomy is a procedure performed by a urologist that involves surgical removal of the testicles through a small scrotal incision. This procedure is done with a particular technique that allows for vaginoplasty later, if desired. Afterward, patients may adjust their dose of estrogens downward and no longer require spironolactone. Recovery takes approximately 2 weeks. Individuals seeking orchiectomy may wish to consider semen banking to preserve future fertility options.
  - **Vaginoplasty**: In addition to an orchiectomy, a person may elect to undergo a vaginoplasty, which is a surgical procedure that involves reconstructing the genitals to create external female genitalia with or without a vaginal cavity.
  - **Phalloplasty:** This surgery involves a multi-staged procedure for the creation of a penis, urinary channel to allow urination, scrotum, and the obliteration of the vaginal cavity with closure. The removal of the female genital organs such as the uterus and ovaries and fallopian tubes are required and usually performed separately and prior to the phalloplasty surgery. The creation of the penis is performed with use of tissue from other parts of the body, which could include, more commonly the radial forearm free flap, or anterolateral thigh flap, and latissimus dorsi (MLD) flap. Prosthetics such as silicone or saline testicles can be placed as well as inflatable penile prosthetics in the final stage.
  - **Metoidioplasty:** In this procedure, the surrounding tissue of the clitoris is released to achieve maximal length and a more natural-looking male position. A urethra is also

reconstructed using either local skin tissue or a graft from the mouth depending on the amount of tissue present. Construction of a scrotum with testicular prosthetics can also be performed at the same time.
- **Hysterectomy:** Removal of the uterus and cervix via laparoscopic or vaginal techniques.
- **Salpingo-oophorectomy:** Removal of the fallopian tubes and ovaries.
- **Vaginectomy:** Obliteration of the vaginal canal and opening.

Is surgery the only treatment for gender dysphoria?

Surgery is just one option. Not everyone who has gender dysphoria chooses to have surgery. Depending on your age and preferences, you may choose:

- Treatment by a licensed mental health care professional that has experience in treating people with gender dysphoria, which is recommend regardless of whether you undergo surgery due to the high risk of anxiety, depression, self-harm, and suicide.
- Hormone replacement therapy to increase masculine or feminine characteristics.
- Another option is _____.

What are some potential complications of surgery to treat gender dysphoria?

Potential complications include:
- Changes in sexual sensation
- Trouble with bladder emptying
- Bleeding
- Infection
- Nerve damage
- Decrease in function
- Poor healing
- Scarring that can cause pain, firmness, asymmetry
- Side effects of anesthesia, including death

What happens after surgery to treat gender dysphoria?

Recovery times vary based on what procedures or combination of procedures you have as follows:

- **Cheek and nose surgery:** Swelling lasts for around two to four weeks.
- **Chin and jaw surgery:** Most swelling fades within two weeks but may take up to four months for swelling to completely disappear.
- **Chest surgery:** Swelling and soreness lasts for one to two weeks with physical limitations lasting at least one month.

- **Bottom surgery:** Most people do not resume usual activities until at least six weeks after surgery and weekly follow-up visits with your surgeon for several months will be necessary.

When should I see my surgeon?

After surgery, you should see your surgeon if you experience:

- Bleeding for more than a few days.
- Pain that does not go away after several weeks.
- Signs of infection, such as a wound that changes color or does not heal.

Please initial each statement on this form to show that you understand the risks and changes associated with gender dysphoria surgeries.

Patient	Statement
	I understand that my surgeon will discuss with me during the preoperative process the available surgical procedures to treat gender dysphoria, the aftercare needs following surgery, and the importance of postoperative follow-up.
	I understand that these surgeries are permanent.
	I understand that if I have my breasts removed, I must undergo reconstructive surgery if I wish to have breasts in the future. If implants are used, complications may include pain, numbness, infection, bleeding, asymmetry, hardening, rippling, scarring, and the possible need for multiple surgeries.
	I understand that if I have my breasts removed that breast feeding will never be possible.
	I understand that if I my breast augmentation surgery, complications may include pain, numbness, infection, bleeding, asymmetry, hardening, rippling, scarring, and the possible need for multiple surgeries.
	I understand that my surgeon will assess me for risk factors associated with breast cancer prior to breast augmentation or mastectomy, including genetic mutations (i.e., BRCA1, BRCA2), family history, age, radiation, exposure to estrogen, and the amount of breast tissue anticipated to remain after surgery.
	I understand that if I undergo metoidioplasty/phalloplasty I will need lifelong urological treatment.
	I understand that complications following metoidioplasty/phalloplasty include: • urinary tract strictures and fistulas • mucoceles due to vaginal remnant • hair growth within the neourethra

	• compromised sexual function including absent tactile and/or erogenous sensation, difficulties achieving orgasm • complications with penile prosthetics
	I understand that if I undergo vaginoplasty I will need lifelong treatment with my surgeon, primary care physician, and/or gynecologist.
	I understand that if I undergo vaginoplasty, complications can include: • the formation of granulation tissue • intravaginal hair growth • delayed wound healing and/or wound disruption • introital stenosis (closing, narrowing, or closure) • painful sex
	I understand that my surgeon may stop further treatment because the risks of treatment outweigh the benefits of treatment.
	I understand that this treatment will not prevent serious psychiatric events, including suicide.
	I agree to tell my surgeon if I have any problems or side effects or am unhappy with the surgery, including if I have worsening signs of depression or anxiety or want to harm myself or attempt suicide.
	I understand that my surgeon may be required to refer me to one or more specialists for surgery-related complications, and I agree to go to those specialists as recommended.
	I acknowledge that surgery to treat gender dysphoria is only part of my overall health and that a range of preventative health activities are recommended including: • cervical/prostrate screening tests at appropriate intervals as recommended by my doctor • regularly checking my breasts for lumps, even if I have had a mastectomy • regular mammograms from an appropriate age in consultation with my doctor • quitting smoking • 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

CONSENT:

My signature below confirms that:

1. My surgeon has talked with me about:
   a. the benefits and risks of surgery to treat gender dysphoria;
   b. the possible or likely consequences of surgery to treat gender dysphoria;
   c. potential alternative treatments.

2. The information provided to me in this form and by the surgeon includes the known effects and risks of surgery to treat gender dysphoria. I know that there may be other unknown short-term and long-term effects or risks

3. I have had sufficient time and opportunity to discuss relevant treatment options with my surgeon.

4. All my questions have been answered to my satisfaction by my surgeon.

5. I know enough to give informed consent to have, refuse, or postpone surgery to treat gender dysphoria.

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 surgeon.

7. My signature below attests to my consent to surgery to treat gender dysphoria.

My signature below confirms the following:

_____ _____

Patient's signature (required) Date

_____ _____

Patient's signature (required) Date

SURGEON:

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

_____
Surgeon's printed name (required)

_____ _____
Surgeon'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 fluid 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

DRAFT FOR JUNE 23, 2023 - JOINT COMMITTEE MEETING

64B8ER-XX/64B15ER-XX - Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults

Pursuant to Section 456.52, Florida Statutes, when sex-reassignment prescriptions or procedures are prescribed for or administered or performed on patients 18 years of age or older, the physician is required to obtain voluntary, informed consent while physically present in the same room as the patient. Consent is not required for renewal of such prescriptions if a physician and the physician's patient have met the requirements for consent for the initial prescription or renewal; however, a separate consent is required for any new prescription for a pharmaceutical product not previously prescribed to the patient.

(1) Informed Consent. The Board has approved the following mandatory informed consent forms for sex-reassignment prescriptions or procedures for patients 18 years of age or older:

(a) For patients prescribed sex-reassignment feminizing medication, form DOH-MQA-XXXX, (06/23), entitled "NAME," which is hereby incorporated by reference and available from http://www.flrules.org/Gateway/reference.asp?No=Ref- and from the Board's website at [DOH LINK].

(b) For patients prescribed sex-reassignment masculinizing medications, form DOH-MQA-XXXX, (06/23), entitled "NAME," which is hereby incorporated by reference and available from http://www.flrules.org/Gateway/reference.asp?No=Ref- and from the Board's website at [DOH LINK].

(c) For patients undergoing surgical treatment, form DOH-MQA-XXXX, (06/23), entitled "NAME," which is hereby incorporated by reference and available from http://www.flrules.org/Gateway/reference.asp?No=Ref- and from the Board's website at [DOH LINK].

(2) A Board-approved informed consent form is not executed until:

(a) The physician issuing the prescription or performing the procedure, while physically present in the same room as the patient, has informed the patient of the nature and risks of the prescription or procedure and has provided and received the patient's written acknowledgement before the prescription is prescribed, administered, or performed. The physician is prohibited from delegating this responsibility to another person. The physician is also required to sign the informed consent form.

(b) The patient is required to sign the informed consent form.

(c) A competent witness is also required to sign the informed consent form.

Rulemaking Authority 456.52 FS. Law Implemented 456.52 FS. History – New____.

Standard of Care for Medical Treatment of Transgender Youth and Adults

1) Background
    a. Treatment of children with gender dysphoria/gender incongruence most commonly begins with early social transition (but not in the original Dutch Protocol as early social transition was discouraged) or late social transition, followed by puberty blocking in Tanner 2-3 puberty, then by cross-sex hormones and in some cases, gender affirming surgeries in a minority of cases in childhood but typically after a child has reached the age of majority.
        i. *This phased approach is not based on a robust scientific evidence base, but rather consensus opinion and limited observational cohort studies with short periods of observation after the interventions. Further, these studies have all lacked control groups even though not all transgender children and adults opt for medical and or surgical treatments. The most recent guidelines from the Endocrine Society published in 2017 rated the existing published evidence to support these clearly risky interventional therapies as low or very low quality and urged the scientific community to conduct more robust research in this area.*
    b. Fundamentally, therefore all four of these treatment modalities are of an **experimental nature when used in adults and children.**
    c. All four of these treatments are experimental in nature because we lack long-term prospective controlled trials which would usually allow a robust detailed ascertainment of the risks and /or benefits of these four interventional, high risk-treatments for gender dysphoria/gender incongruence.
    d. Finally, there are no well-done comparative studies to no medical treatment, psychological support with hormones, or exploratory psychodynamic therapy alone or in combination with hormonal treatments.
2) Definitions
    a. Cisgender: This means not transgender
    b. Gender Reassignment: This refers to the treatment procedure for those who want to adapt their bodies to the experienced gender by means of hormones and/or surgery.
    c. Gender-reassignment surgery: These terms refer only to the surgical part of gender confirming\gender affirming treatment.
    d. Gender Dysphoria: This is the distress and unease experienced if gender identity and designated gender are not completely congruent.
    e. Gender Incongruence: This is an umbrella term use when the gender identity and/or gender expression differs from what is typically associated with the designated gender. Gender incongruence is also the proposed

name of the gender identity related diagnoses in ICD-11. **Not all individuals with gender incongruence have gender dysphoria or seek treatment**.

f. Transgender: This is an umbrella term for people who have a gender identity and/or gender expression that differs from what is typically associated with their sex designated at birth. Not all transgender individuals seek treatment.
g. Transgender males (Transmales): This refers to individuals assigned female at birth but who identify and live as men.
h. Transgender woman (Transfemales): This refers to individuals assigned male at birth but who identify and live as women.
i. Transition: This refers to the process during which transgender persons change their physical, social, and/or legal characteristics consistent with the affirmed gender identity. Prepubertal children may choose to transition socially (this was expressly discouraged in the Dutch protocol).

3) Psychiatric Support *(Adapted from the 2017 Endocrine Society Guidelines)*
   a. **Mental Health Providers (MHP) Adults**: We determine that only trained mental health professionals (MHPs) who meet the following criteria should diagnose gender dysphoria (GD)/gender incongruence in adults: (1) competence in using the Diagnostic and Statistical Manual of Mental Disorders (DSM) and/or the International Statistical Classification of Diseases and Related Health Problems (ICD) for diagnostic purposes, (2) the ability to diagnose GD/gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (3) training in diagnosing psychiatric conditions, (4) the ability to undertake or refer for appropriate treatment, (5) the ability to psychosocially assess the person's understanding, mental health, and social conditions that can impact gender-affirming hormone therapy, and (6) a practice of regularly attending relevant professional meetings. **Mental Health Providers (MHP) Children**: We determine that only MHPs who meet the following criteria should diagnose GD/gender incongruence in children and adolescents: (1) training in child and adolescent developmental psychology and psychopathology, (2) competence in using the DSM and/or the ICD for diagnostic purposes, (3) the ability to make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder, sexual trauma, internalized homophobia, autism spectrum disorder, etc.) (4) training in diagnosing psychiatric conditions, (5) the ability to undertake or refer for appropriate treatment, (6) the ability to psychosocially assess the person's understanding and social conditions that can impact gender-affirming hormone therapy, (7) a practice of regularly attending relevant professional meetings, and (8)

knowledge of the criteria for puberty blocking and gender-affirming hormone treatment in adolescents.

b. **Medical Treatment Standards**: **First,** we forbid puberty blocking and gender-affirming hormone treatment in prepubertal children with gender dysphoria/gender incongruence. **Second,** we mandate that clinicians inform and counsel all individuals seeking continuation of gender-affirming medical treatment regarding options for fertility preservation prior to continuing puberty suppression or cross-sex hormones or hormone antagonist therapy in adolescents. **Third,** in adolescents who request continuation of cross-sex hormone treatment (given this is a partly irreversible treatment), we mandate using a gradually increasing dosing schedule of testosterone or estrogen treatment only after a multidisciplinary team of medical and MHPs has confirmed the persistence of GD/gender incongruence and sufficient mental capacity to give informed consent, which adolescents have typically by the age of 16 years. It must be understood that earlier use of cross-sex hormones is based on very little empirical data. As an example, the Trans Youth Care Study which used cross sex hormones in younger transgender youth than the Dutch protocol where cross-sex hormones were used ~16 years of age documented rates of completed suicide and suicidal ideation that were ~21x higher than the general population of children/adolescents. **Fourth,** we mandate monitoring clinical pubertal development every 6 months and laboratory parameters every 3 months during sex hormone treatment in all youth. **Fifth,** at every visit we expect prescribing physicians to review all possible, unexpected and expected side effects and help these patients manage the consequences of any side effects related to medical treatment. **In adults treated with any hormonal therapy we**: **First,** we mandate that clinicians confirm the diagnostic criteria of GD/gender incongruence and the criteria for the endocrine phase of gender transition before beginning treatment. **Second**, we mandate that clinicians evaluate and address medical conditions that can be exacerbated by hormone depletion and treatment with sex hormones of the affirmed gender before beginning treatment. **Third,** we mandate that clinicians measure hormone levels during treatment to ensure that endogenous sex steroids are suppressed and administered sex steroids are maintained in the normal physiologic range for the affirmed gender. **Fourth,** we mandate that prescribing physicians or endocrinologists provide education to transgender individuals undergoing treatment about the onset and time course of physical changes induced by sex hormone treatment and review possible, unexpected and expected side effects and help these patients manage the consequences of any and all side effects possibly related or reasonably related to treatment. These discussions and review of side effects must be noted in the medical record as well.

c. **Informed consent (IC) and assent:** must be obtained in all children at 2-4 weeks before initiation and every 6 months thereafter. These consents must be signed by all legal guardians and verbal assent of the child before continuing therapy. All subsequent visits must include a system wide review of all adverse effects and plans to care for any complications or side effects that arise during treatment. In adults only IC will need to occur yearly with review of any side effects in each clinic visit and noted in the record of follow up care as well.
d. **The IC process should be occurring simultaneously while non-judgmental exploratory psychotherapy** has been ongoing for at least 6-12 months with multiple sessions each month before any escalation of therapy.
e. **Ongoing medical treatment:** cannot continue to occur if the child or adult with gender dysphoria is suffering from any other active psychopathology. As in the Dutch protocol these children and adults must be stable psychologically with adequate treatment of any ongoing psychiatric co-morbidities and under adequate control to continue with medical treatment.
f. **It must be explicit that all medical treatment with gonadotropin releasing hormone agonists, or any cross-sex hormones or other hormonal therapies used in children are experimental in nature:** and may not be safe nor effective in alleviating all symptoms of gender dysphoria/gender incongruence while potentially:
    i. predisposing the child to persist in their gender dysphoria long-term (classic boys with early onset dysphoria have very high desistance rates near 85% according to the 2017 Endocrine Society guidelines).
    ii. lead to physical changes in their body which are irreversible.
    iii. result in persistent medical risks that may increase over time, both in the short-term and long-term,
    iv. resulting in numerous multi-system health effects that could be life threatening.
    v. potentially lead to serious challenges in daily health, activities of daily living, psychological and social functioning. **They may die despite taking this gender affirming hormonal interventions.**

f) **Any physician in the state of Florida who prescribes any medical treatments for the purpose of sex-reassignment in children or medical and/or surgical treatments related to sex-reassignment in adults with gender dysphoria/gender incongruence** must: strive to follow that patient throughout their treatment course and serve as the "physician of record" to always help that individual patient for any reason that is reasonably related to the prescribed medical therapies they received even if: At 18 to 21 years of age they need to formally transfer

that care to an adult physician skilled in this area. *This continuity of care mandate always applies:*

vi. Even if they should decide to persist or desist in their gender dysphoria and any related medical treatments.
vii. Even if it is difficult for that physician to see these patients to deal with all adverse outcomes or complications of any hormonal treatments.
viii. Even if that prescribing physician needs to collaborate or coordinate and/or refer to any other licensed physician who agrees to see that patient, to deal with any complications that may arise from any medical treatment or treatments to align primary or secondary sexual characteristics with the preferred gender of the patient.
ix. While expecting that all physician complaints coming from anyone in the health care system, or from the patient, or their families, will need to be processed by the DOH and then the respective boards of medicine or osteopathic medicine will determine if there has been any poor adherence to the standards of practice elated to continuity of care for children and adults with gender dysphoria. *It is essential that any transgender patient be able to easily report to the DOH, if they are not getting adequate medical support and care for any clinical care or related complications reasonably resulting from medical treatments prescribed for gender dysphoria.*

h) **Medical therapy with gonadotropin releasing hormone agonists** in children may only occur in children for up to 24-months in total as they have not been studied robustly in children for this reason for more than that.

i) **All surgical procedures will be forbidden in children less than 18 years of age.** Separate adult consent forms will need to be signed before proceeding with any gender affirming surgeries of any kind.

j) **IC and assent document will be made to detail all known, potential and theoretical risks related to medical experimentation** with cross-sex hormones and puberty blockers in children and adults with gender dysphoria.

k) **The psychologist/psychiatrist must provide a letter 1)** documenting that the child or adult meets the criteria for gender affirming hormonal therapy for adolescents or adults. **Second,** they need to confirm that there are no active psychological conditions present in the patient which could be confounding a reliable diagnosis of gender dysphoria/gender incongruence and that the patient is stable psychologically to make an informed decision regarding these experimental therapies.

l) **Criteria for gender affirming hormone therapy for adults:** 1) persistent, well-documented gender dysphoria/gender incongruence 2) the capacity to make a fully

informed decision and to consent for treatment 3) the age of majority of at least 18 years of age 4) mental health concerns have been stable and well-controlled for the last 6 months.

m) ***Baseline and Follow Up-Protocol During Suppression of Puberty in Children****: These data must be collected*

Every 3 months	***Every 6 months***	***Yearly Assessments***
Anthropometry	*LH, FSH (Pediatric Highly Sensitive Assay)*	*Bone Density Lumbar Spine and Whole Body DEXA*
Height/Weight/Sitting Height	*Estradiol/Testosterone (LC/MS/MS)*	*Bone Age Left Hand Until Growth Plates Fused*
Blood Pressure	*25-hydroxyvitamin D*	***Depression Screening***
Tanner Staging	*CBC/CMP*	***PHQ-9***

n) **Baseline and Follow-up Protocol During Induction of Puberty**

Every 3 months	***Every 6 months***	***Yearly Assessments***
Anthropometry	Transmales: CBC, Lipid Panel, Testosterone (LC/MS/MS), 25-hydroxyvitamin D Transfemales: Prolactin, Estradiol (LC/MS/MS), 25-hydroxyvitamin D	DEXA BMD Lumbar Spine and Whole Body
Height/Weight/Sitting Height		Bone Age Until Growth Plates Fused
Blood Pressure	***Depression Screening PHQ-9***	
Tanner Staging		

o) **Follow Guidelines from the 2017 Endocrine Society Guidelines "Endocrine Treatment of Gender-Dysphoric/Gender Incongruent Persons: An Endocrine Society Clinical Practice Guideline" for all adults: (JCEM, November 2017, 102(11):3869-3903 noted in Tables 14 and 15.**

Informed Consent for Adults with Gender Incongruence Seeking Medical Treatment (See Table 1 Summary of Side Effects)

I. Medical Risks Associated with Sex Hormone Therapy

a. **Transgender Female**: Estrogen

i. It is important that you understand that the feminizing effects of estrogen can take several months to be noticeable and several years to be complete and **some of these changes will be permanent or irreversible**:

1. Breast development will vary from person to person and after stopping estrogen the breasts may shrink but will not completely disappear.
2. These hormones have not been studied in gender dysphoria and to transition in this way and the impacts of sex hormones on brain structures in your brain is impossible to predict.
3. Changes in fertility and sperm production will occur and likely be permanent.

ii. **Some changes may not be permanent** if stopping estrogen:

1. Decreased acne.
2. Male pattern balding stops or slows.
3. Skin may be softer.
4. Fat redistribution to a female pattern with less abdominal fat, with more fat on the buttocks and thighs

iii. Estrogen may cause or contribute to depression, and it is important to stay in therapeutic relationship with your psychologist.

iv. Estrogen treatment will not protect you from sexually transmitted diseases like HIV.

v. Yearly breast exams after 40 years of age are mandatory. Please examine your breasts monthly and notify your physician if you feel any masses in the breasts.

vi. Inform your physician of all medications you are taking, herbal supplements, hormones, or recreational drugs you are taking.

vii. Individual responses to estrogen can be highly variable and it is important you take your estrogen as prescribed by your physician.

viii. You will need yearly physical exams and labs about twice yearly to monitor you for side effects while on estrogen treatment and even after stopping.

ix. If you ever want to stop estrogen it is important you do so as safely as possible and not abruptly, with guidance and monitoring of your physician.

x. Estrogen treatment will shrink the testicles by about 40% and decrease natural testosterone levels causing these impacts on your brain, testicles and penis:

1. You will have fewer erections; morning erections and penetrative sex may be difficult or impossible.
2. Sperm may still be present, but they may not develop impacting your fertility potentially forever.
3. Your mental drive for sex will decrease.

xi. Very High Risk of Blood Clots which can lead to Thromboembolic Disease
   1. This may result in your early death if you have a deep vein thrombosis or a pulmonary embolism.
   2. You may develop chronic vein problems in the legs.
   3. You may have a stroke which may lead to early death, brain damage, paralysis, blindness, or difficulty walking.
   4. <u>The highest risks with estrogen are as follow and if you have these please discuss with your physician:</u>
      a. <u>If you smoke cigarettes.</u>
      b. <u>Are overweight.</u>
      c. <u>Over 40 years of age</u>
      d. <u>Have a history of blood clots before estrogen treatment.</u>
      e. <u>Have high blood pressure already.</u>
      f. <u>Prior estrogen dependent cancer</u>

xii. Moderate Risk of:
   1. Macroprolactinoma (20%)
   2. Breast Cancer
   3. Prostate Cancer
   4. Heart Attacks (greater risk if smoking)
   5. Strokes (greater risk if smoking)
   6. Gall Bladder Disease
   7. Elevated Triglycerides
   8. Increased Blood Pressure
   9. Liver Disease and inflammation of the liver labs will need to be checked regularly.
   10. Migraine Headaches may increase with estrogen treatment, and this may be a reason to discontinue estrogen after talking with your physician.
   11. Nausea and vomiting like morning sickness in pregnancy. You could get dehydrated and must let your physician know if this happens.
   12. Estrogen may prevent prostate problems, but it may also cause growth of the prostate. Some transwomen have had prostate cancer diagnosed later and at a later stage with poorer survival when compared to cisgender men.

b. **Transgender Male**: Testosterone:
    i. This may cause changes in brain structures, and this has not been scientifically studied and effects are impossible to predict.
    ii. You should follow your prescribed dose of testosterone to try and keep levels in the normal range for men.
    iii. Please keep your appointments, physical exams and get the labs done or this could jeopardize prescription refills.
    iv. There are medical conditions that could make testosterone therapy dangerous or physically damaging. This should be reviewed with your prescribing physician.
    v. You may stop your testosterone at any time, but this should be done with adequate medical supervision and not abruptly. You should discuss stopping at any visit with your prescribing physicians help to do so safely.
    vi. Very High Risk of Adverse Outcomes
        1. Elevated Red Blood Cells (Hematocrit > 50%)
    vii. Moderate Risk of Adverse Outcomes:
        1. Severe Liver Dysfunction and Damage
        2. Heart Attacks
        3. Strokes
        4. Hypertension
        5. Breast or Uterine Cancer
        6. Infertility (undergo egg banking if you want to preserve fertility) you may be unable to ever get pregnant.
        7. Increased Risk of Diabetes Mellitus
        8. This will not protect you from sexually transmitted diseases.
        9. Treatment may increase estrogen in your body and impact potential risk of breast cancer.
        10. Cholesterol and Lipids: lower HDL your good cholesterol and raise the LDL your bad cholesterol.
        11. Increase Risks of Heart Attacks and Strokes
        12. May make changes in your mood and emotions and you may need psychological support to deal with these changes.

II. **Testosterone Treatment in Transgender Males** may take up to 5 years to be complete and some of these changes will be permanent (irreversible) and some may not be permanent including:
a. Increased muscle mass
b. Changes in fat mass-fat may look more like a male pattern with increased abdominal fat, with decreases in breast, buttock and thigh fat)
c. Increased facial hair and acne (irreversible)
d. Male-pattern baldness (irreversible)
e. Increased sexual desire.
f. Enlargement of your clitoris (irreversible)

g. Temporary or permanent decrease in fertility or infertility (irreversible)
h. Deepening of the voice (irreversible)
i. Cessation of menses
j. Increase in body hair on the face, chest, and abdomen (irreversible)
k. Heavy Uterine Bleeding
l. Hair loss especially in my temples and crown of your head (permanent)

III. **Estrogen Treatment in Transgender Females** is much more complex:
a. Harder to suppress testosterone levels to female physiological range.
b. Often, other medications are used to reduce testosterone concentrations to the female range.
    i. Progestins
    ii. GnRH agonists (puberty blockers)
    iii. Cyproterone Acetate (not in the USA)
    iv. 5 alpha-reductase inhibitors do not lower testosterone well.
c. Oral or Transdermal Estrogen Risks:
    i. Increased Risk of blood clots with oral more so than transdermal
    ii. Avoid ethinyl estradiol.
    iii. Oral or transdermal 17-β Estradiol may be safer.
d. Physiological Concentrations of Sex Hormones is mandated in both genders.
e. Parenteral or Transdermal Testosterone is Safer for Liver Toxicity
f. Synthetic Forms of Testosterone should be avoided particularly 17-alkylated forms which are more slowly degraded by the liver including danazol, methandrostenolone, methyltestosterone, oxymethalone and stanozol.

IV. Risk of Venous Thromboembolism in Transfemales
a. 20-fold increased risk in a Dutch study using ethinyl estradiol but this has not been consistently observed in other studies when compared to that seen in cisgender women
b. Those with a history of VTE should get screening like the general population.

V. Estrogen can increase growth or pituitary lactotroph cells increasing risk of a large prolactinoma or just elevated prolactin.
a. Prolactin should be measured at baseline and then every 6 months to 12 months thereafter.
b. Those treated with psychotropic medications this may also lead to higher prolactin levels.

VI. Testosterone administration to transmales leads to a more atherogenic lipid profile that may increase the risk of heart attacks or strokes.
a. Higher LDL or bad cholesterol
b. Lower HDL
c. Higher triglycerides

d. While the rates of CVD in transmales is not clear more data is needed to better understand these risks
e. Avoiding smoking and getting regular exercise and a healthy low fat, low saturated fat diet may help modify these risks.

VII. Estrogen administration to transfemales leads to more favorable changes in lipid profle with increased HDL, and decreased LDL.
   a. However, increased weight, blood pressure and markers of insulin resistance may counteract the changes in lipid profile and increase risks of cardio-vascular diseases long-term.

VIII. Adequate testosterone treatment in transmales may help maintain bone mass and low levels of sex hormones may be associated with bone loss. Testosterone conversion to estrogen may be a reason why bone health with adequate testosterone treatment is possibly protective.

IX. Transfemales more commonly have low BMD T-scores of -2.5 in about 20% of cases.

X. Fracture Data is not available in transmales or transfemales. Further many now starts these transitions earlier in childhood which may confound fracture predictions models like FRAX.

XI. Transfemales are at risk for Breast Cancer and Prostate Cancer, and you should be screened. Rates of prostate cancer are lower than cisgender males but some cases in transgender people were found at later stage of disease so early screening and exams seem important to assess this risk. It has been shown that transfemales may survive prostate cancer less frequently than cisgender males.

XII. Breast Cancer does occur in transfemales and even less commonly in transmales. Longer term studies are needed to better understand these risks.

XIII. Sexual Function is certainly a complication of manipulation of these hormonal systems. Further, the sexual orientation and type of sexual practices you desire to participate in will be important to discuss with your physicians and surgeons should you consider gender affirming surgery.

XIV. Table 1 details the potential, known and theoretical risks related to treatment in children and adults who proceed through typical treatment protocols with hormones such as GnRH agonists and cross-sex hormones but do not include risks of surgeries.

XV. Lastly one of the longest-term studies looked back al all adults who had gender affirming surgery and hormonal treatments in Sweden and reported on their health over a 30-year period. This study showed death that was much earlier in the transmale and transfemale population and their lifespan was much shorter than the general population in Sweden (See Figure 1).

Informed Consent for Children and Adolescents Seeking Medical Therapy of Gender Dysphoria or Gender Incongruence

Background:

a. Treatment of children with gender dysphoria/gender incongruence most commonly begins now with early social transition (but not in the original Dutch Protocol as early social transition was discouraged) or late social transition, followed by puberty blocking in Tanner 2-3 puberty, then by cross-sex hormones and in some cases, gender affirming surgeries in a minority of cases in childhood but typically after a child has reached the age of majority.
    x. *This phased approach is not based on a robust scientific evidence base, but rather consensus opinion and limited observational cohort studies with short periods of observation after the interventions. Further, these studies have all lacked control groups despite the fact that not all transgender children and adults opt for medical and or surgical treatments. The most recent guidelines from the Endocrine Society published in 2017 rated the existing published evidence to support these clearly risky interventional therapies as low or very low quality and urged the scientific community to conduct more robust research in this area.*
b. Fundamentally, therefore all four of these treatment modalities are of an experimental nature when used in children.
c. All four of these treatments are experimental in nature because we lack long-term prospective controlled trials which would usually allow a robust detailed ascertainment of the risks and /or benefits of these four interventional, high risk-treatments for gender dysphoria/gender incongruence.
d. Finally, there are no well-done multi-arm controlled comparative studies to no medical treatment, psychological support with hormones, or exploratory psychodynamic therapy alone or in combination with hormonal treatments compared with current gender affirmative care.

Summary of Potential Risks and Benefits:

Possible Benefits: The psychological benefits of medical transition among youth with gender dysphoria and gender incongruence is not entirely clear. The recent trans youth care study (See Figure 2) which was following a group of children and adolescents for about 2 years after initiation of gonadotropin releasing hormone agonist followed by cross sex hormones showed very modest changes (See Figure 3) in psychological and social functioning. Furthermore, they noted a large portion of their study population who had suicidal ideation and 2 out of 300 patients who had completed suicide numbers that are much higher than what is seen in the general adolescent population (See Figure 4).

Possible Risks: (Bone) Medical treatment in children with gender dysphoria by utilizing gonadotropin releasing hormone agonist as well as cross sex hormones has significant risks associated with it. First it can have a significant adverse impact on bone mineralization. At baseline studies have shown that children with gender dysphoria have lower than average bone mineral density in both genders. Furthermore, data in the trans female population does not show full recovery and risks of spinal fracture and long bone fractures as well as osteoporosis remains a long-term risk of these treatments. **(Fertility):** Long-term studies on fertility in children treated with gonadotropin releasing hormone agonist and cross sex hormones is unclear. There is a high risk of infertility and polycystic ovarian syndrome among trans males. There is also a very high risk of infertility in trans females as high doses of estrogen will likely impact testicular function long-term.

Table 1: Potential, Known and Theoretical Side Effects in Children and Adults with Gender Dysphoria related to GnRH agonists, Cross Sex Hormones and Other Hormone Related Treatments

Transmale Side-Effects	**Treatment Related Symptoms**	**Transfemale Side-Effects**	**Treatment Related Symptoms**
Infertility	Unable to or Harder to Get Pregnant	Smaller Testicles & Infertility	Unable to or Harder to get Partner Pregnant
Severe Liver Dysfunction	Cessation of Menses	Increased Risk of Thromboembolic Disease	Decreased Sexual Desire
Erythrocytosis	Increased Facial and Body Hair	Macroprolactinoma (20%)	Decreased Spontaneous Erections
Increased Coronary Artery Disease	Increased Skin Oils	Breast Cancer	Decreased Facial and Body Hair
Increased Cerebrovascular Disease	Increased Muscle Mass	Coronary Artery Disease	Decreased Oily Skin
Hypertension	Reduced Fat Mass	Cerebrovascular Disease	Increased Breast Growth
Breast and Uterine Cancer	Deeper Voice	Cholelithiasis	Reduced Fat Mass
Death by Suicide	Clitorimegaly	Hypertriglyceridemia	
Death by Cardiovascular Disease	Male Pattern Hair Loss	Death by Cardiovascular Disease	Decreased Testosterone
Death by Neoplasm		Death by Neoplasm	Decreased Sperm Production
Need for Psychiatric Hospitalization		Need for Psychiatric Hospitalization	Scalp Hair Changes
Substance Abuse		Substance Abuse	Voice Changes
Smoking		Smoking	
Suicide Attempt		Suicide Attempt	
Criminal Activity		Criminal Activity	

Detailed Explanation and Expectations of Hormonal Treatments in Gender Incongruence

I. This informed consent form is based largely on the 2017 Endocrine Society Clinical Practice Guidelines which rated the evidence related to the medical care of children and adults with gender dysphoria and gender incongruence. **They stated that the purpose of these guidelines was to make detailed recommendations and suggestions based on "existing medical literature and clinical experience that will enable treating physicians to maximize benefit and minimize risk".**

a. You must realize that the science in this area is unsettled and there are very high health risks associated with these treatments. Most of the recommendations in the Endocrine Society 2017 guidelines are based on mostly low and very low-quality data.
b. Fundamentally, these treatments are of major physical health and mental health consequences, while posing serious risk of side effects with little data supporting major clinically significant improvements in future potential of the treated gender dysphoric individuals to thrive physically, emotionally, socially, and sexually as a person (See Figures 2-4).
c. These same guidelines stated when they were written: **"in the future, we need more rigorous evaluation of the effectiveness and safety of endocrine and surgical protocols (pp.3874)".**
d. Multiple robust systematic reviews of the safety and efficacy data in this area have not confirmed support for these same medical and surgical treatments.
e. Recently in the last year or two, the United Kingdom, Sweden, Finland, and other nations have heavily restricted the clinical use of gonadotropin releasing hormone agonists to research protocols in children with gender dysphoria while calling for more robust safety and efficacy data which should only then form the basis for more widespread use in children of what remains experimental therapy.
f. *We have seen widespread clinical diffusion and premature application of these therapies worldwide since 2014 before there was good data that they were safe and effective both in the short term and the long term*.

II. Unknowns in the use of these medications in adults and children with gender incongruence are:

a. The effects of prolonged pubertal delay in adolescents on bone health, ovarian and testicular function, and brain development including the effects on cognitive, emotional, social, and sexual development.
b. The effects of treatment in adults or children on sex hormone levels
c. The requirement for and effects of progestins and other agents to suppress your own sex hormones during treatment.
d. The risks and benefits of gender-affirming hormone treatment in adult and pediatric transgender people (Table 1 Lists Potential Side Effects)

III. From the 2017 Endocrine Society Guidelines, **"In cases where severe psychopathology, circumstances or both seriously interfere with the diagnostic work up or make satisfactory treatment unlikely, clinicians should assist the adolescent in managing the other issues. Literature on postoperative regret suggests that besides poor quality of surgery, severe psychiatric comorbidity and lack of support may interfere with positive outcomes."**

IV. Earlier data suggests that about 85% of prepubertal children with childhood onset gender dysphoria were not gender incongruent in adolescence. However, most of these reported cases were in boys (2-6 boys for every female). Now we are seeing older adolescent girls (3 girls to every 1 boy) or young adults, presenting to clinics with gender incongruence and we are not sure if these same rates of desistance will be observed in what is a different population now.

V. Significant mental health problems at baseline were forbidden in the Dutch protocol to allow a gender incongruent person to proceed with medical treatment. Now we are seeing reports of individuals with gender incongruence with serious mental health issues and neurodevelopmental issues such as autism and ADHD being frequently transitioned. These other aspects of a person's psychological state may unnecessarily complicate the diagnosis of gender dysphoria and subsequent treatment trajectory. The safety and efficacy are unclear because the populations are different than those studied by the Dutch protocol which forms the bases of gender affirming hormonal treatments.

VI. There has been a marked increase in the numbers of people presenting to gender clinics worldwide since 2014. Possible reasons exist for why we are seeing such a rapid growth in cases:

a. Increased acceptance of gender diversity (Nature Review Steven Rosenthal 2021)
b. Transgender and Gender Diverse now has much broader meaning than previously.
c. There are cases reported which highlight that the massive epidemiological changes in the prevalence and incidence of new cases is buried in maladaptive coping mechanisms of individuals coupled with social and peer influences (Sarah Jorgensen Archives of Sexual Behavior 2023).
d. It is important for you to understand that sometimes a transgender identity can form in the context of family dysfunction, psychosocial issues, sexual assault, and other related trauma. **Further heavy engagement in social media has contributed to people of the same peer group all presenting with gender dysphoria. This is the reason that long term psychological support and non-judgmental psychotherapy is an important part of your evaluation before proceeding with medical**

treatments which have major long term and short-term side effects. Some of these side effects are permanent.

e. Feeling uncomfortable in your body is not uncommon in adolescence and is commonly seen in autism, anxiety disorders, eating disorders or other traumas. This further supports the need for thorough psychological evaluation before considering medical treatments. Hillary Cass in 2022 called this "diagnostic overshadowing". Many young people have fluid identities in other areas that evolve over time in response to various biological, psychological, and social factors (Sarah Jorgensen Archives of Sexual Behavior 2023).

VII. Many individuals are simply same sex attracted as adults and were gender dysphoric in childhood. There are published cases where these people had serious regret and/or desistance after medical therapy, and they still have problems with medical complications, social and sexual functioning as same sex attracted adults.

VIII. The Dutch protocol avoided early social transition because they did not want to reduce the natural desistance rates of 61-98% observed in studies of mostly early onset boys with gender dysphoria. **Living your life as a transgender person may be the right option for some people, but it is important you understand the risks and challenges of this life and these treatments for you lifelong.**

IX. Those of you who start gonadotropin releasing hormone agonists existing data supports the concept that almost all of you (>95%) will progress to cross-sex hormones which then also have their own set of additional and permanent and/or transient side effects with very serious life-threatening consequences.

X. Regret and Desistance: While historical data suggests that rates of regret and desistance after medical treatment of gender dysphoria are < 1% it is important you realize that these published rates occurred during a time when the protocols to treat made it harder to do so. In the Dutch protocol mostly, boys were treated who had early onset gender dysphoria and no co-morbid mental health issues followed by serious dysphoria at pubertal initiation. These stricter protocols are no longer the normative applied standard in many gender clinics. In these earlier studies, regret was defined by interviews of patients or chart reviews looking for expressed regret by patients or those asking for surgical reversals. This may have underestimated the frequency of regret and desistance observed in these earlier studies. Since then, more recent data supports the notion that:

a. many studies have 20-60% of patients lost to long term follow up, so it is hard to be certain of long-term side effects such as medical or surgical complications or certainty about how common regret or desistance is after medical therapy.

b. more recent data looking at more adolescent onset gender dysphoria reports much higher rates of regret and desistance. Rates of desistance range from 6.9-30% where it has been observed that stopping hormone therapy is much more frequent and as many as 22% disengaged from care altogether. If this happens to you, we want you to feel the courage to get continued support from your gender clinic so they can help you deal with any complications which may arise from your treatment whether they be medical, surgical or psychological.
c. A study from the US military healthcare system found that among 952 children and adults treated with hormones for gender dysphoria 29% discontinued medical treatment within four years.
d. The meaning of the terms "regret" and "desistance" can mean different things to different people.:
    i. For many people who have *transient desistance* they express *external forces* that have pushed them to this such as discrimination, family pressure, difficulty finding employment, loss of health insurance, and some of these people decided to reidentify as transgender. This is a possibility for you.
    ii. A second group of people who desist and return to their birth sex identity because of their own *internal factors* which have included things like worsening mental health, realization that gender dysphoria was a maladaptive response to trauma, misogyny, internalized homophobia, or pressures from on-line communities or social media. Unique to this second group of patients is the recollection that these people deeply regretted their transition and expressed that they were harmed by the medical system and hospitals that treated them (Sarah Jorgensen Archives of Sexual Behavior 2023). This is a possibility for you as well.
        1. **Many of these patients are now in litigation against those doctors and hospitals who they feel have harmed them with too cursory of mental health evaluations and observed diagnostic overshadowing that maximized clinical focus on gender over other equally important aspects of a person's being.**
    iii. Other studies have reported reasons for regret and desistance as well to include:
        1. Physical or mental health concerns
        2. Surgical complications
        3. Postoperative pain
        4. Unsupportive parents or romantic partner
        5. Employment difficulties
        6. Challenges Accessing Healthcare
        7. Gender Dysphoria was related to other issues (71%)