Injectable GnRH Analog interferes with fertility, it does not affect the ability to get a sexually transmitted infection ("STI"). Precautions against getting an STI must still be taken.

_____ _____ I understand that the use of an Injectable GnRH Analog in adolescents with gender dysphoria is off- label use. I know this means the medication is not approved by the FDA for this specific diagnosis.

Risks of Treatment of Suppression of Puberty

_____ _____ I understand that information on adverse effects and safety of an Injectable GnRH Analog used in transgender youth is not well known.

_____ _____ I realize that this treatment may not necessarily prevent serious psychiatric events such as a suicidal attempt.

_____ _____ I understand that the treatments may cause weight gain.

_____ _____ I understand that the treatments to suppress puberty may decrease bone density and increase fracture risk.

_____ _____ I understand that my child may grow less than his/her peers while on these medications.

_____ _____ I understand there is a chance that a person taking an Injectable GnRH Analog can develop an allergy to the medication, which presents as a red, painful sterile abscess (boil) at the injection site. This may start out gradually and get worse with each injection. Rarely, the abscess will have to be drained by incision. If a person develops this problem, the Injectable GnRH Analog must be stopped, and there may not be an alternate medication.

_____ _____ I understand that physical examinations and blood tests are needed on a regular basis to check for the effects of an Injectable GnRH Analog.

_____ _____ I understand that an Injectable GnRH Analog can interact with other medications, dietary supplements, herbs, alcohol, and street drugs. I understand that being honest with my care provider about what else I am taking will help prevent medical complications that could be serious.

_____ _____ I understand there could be a stalling of typical adolescent cognitive or brain development while on these medications.

_____ _____ I understand that stopping the development of puberty for my child may

have social consequences.

_____ _____ I understand that my doctor may suggest I stop taking an Injectable GnRH Analog if there are severe side effects or health risks that can't be controlled.

Requirements of Treatment of Suppression of Puberty

_____ _____ I understand and agree with all the requirements explained above, in order to receive suppression of puberty therapy in our program.

_____ _____ I understand that if my child's mental health team and/or treating physician recommends treatment be stopped because the benefits of treatment no longer outweighs the risks, my child has insufficient social or psychological support, or Nemours' program requirements to treat are not met, that Nemours retains the prerogative to discontinue drug therapy.

_____ _____ I understand that I am responsible for the cost of the medical management, including medical appointments, psychological evaluations, laboratory and imaging tests, as well as drug therapy.

_____ _____ I understand that I can change my mind and withdraw consent for further treatment at any time.

_____ _____ I agree to tell a member of my child's treatment team if I think my child has any problems or is unhappy with the treatment.

_____ _____ I understand that after my child turns age18, medical care must be transitioned to an adult endocrinologist.

Prevention of Complications while under Treatment of Suppression of Puberty

_____ _____ I agree to tell my health care provider if my child has any problems or side effects or is unhappy with the medication, and in particular, if I have concerns that my child has worsening signs of depression or anxiety, or wants to harm him/herself or attempt suicide.

_____ _____ I understand my child needs periodic medical evaluations clinic to make sure that my child is responding appropriately. This includes clinic visits with the pediatric endocrinologist every 3 months, laboratory and imaging tests.

_____ _____ I agree to have my child on continued psychological therapy or counseling with the frequency recommended by his therapist

PARENTAL CONSENT:

My signature below confirms that I have read the above, or had it read to me, and that I understand the information and was given the opportunity to ask questions and that all of my questions were answered to my satisfaction. Furthermore, my child's health care provider has discussed:

- The benefits and risks of puberty blockers for my child.
- The possible or likely consequences of using puberty blockers.
- Potential alternative treatments.
- I understand the risks that may be involved.
- I know that the information in this form includes the known effects and risks. I also know that there may be unknown long-term effects or risks.
- I agree with the requirements that must be met before and during treatment to receive puberty blockers in this program.
- I have had sufficient opportunity to discuss treatment options with my child's health care provider.
- I believe I know enough to give informed consent for my child to take, refuse, or postpone using puberty blocking medications.
- My child is in agreement with this treatment and the signature of my child on the assent form attests to this agreement.
- My signature attests to my consent for my child to begin treatment for suppression of puberty.

Based on all this information:I want my child to receive puberty suppression treatment using an Injectable GnRH Analog as Prescribed.

_____	_____	_____
Name of Parent/Legal Representative (Print)	Signature of Parent/Legal Representative	Date / Time
_____	_____	_____
Name of Parent/Legal Representative (Print)	Signature of Parent/Legal Representative	Date / Time

ASSENT OF A MINOR:

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

_____	_____	
Minor's Name (printed)	Minor's Signature	Date / Time
_____	_____	_____
Name of Physician or Designee Obtaining Permission (Print)	Signature of Person Obtaining Permission	Date / Time
_____	_____	_____
Name of Witness (Print)	Signature of Witness	Date / Time

For patients whose primary language is not English:

I certify that I am fluid in English and in the native language of the person(s) 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 Signature	Interpreter's Name (Print)	Date

Puberty Suppression Treatment for Patients with Gender Dysphoria Patient Information and Informed Parental Consent and Assent for Minors

Before a minor continues treatment to suppress puberty with puberty blockers, parents and the guardian and the minor need to be aware of the short- and long-term effects and risks associated with the use of these medications.

The prescribing physician will make a medical decision in consultation with the parents or guardian about the medications that are best for the minor patient. Both the doctor and the parents will keep in mind the minor's physical and mental health during the treatment process. The prescribing physician will discuss with you all of the available information relating to the use of puberty blockers which is a form of hormone therapy. You are asked to read and understand the following information and to discuss any questions you have with your prescribing physician.

You should understand that medical treatment of minors with gender dysphoria is based on very limited research. In some physicians' minds, however, puberty blockers are a reasonable choice considering the parents' and child's wish to delay the onset of puberty. Data supporting this recommendation is very limited. There are few studies examining the mental health of minors who received this treatment and subsequent cross-sex hormones. There are at least six separate studies, done in different nations, that have viewed the totality of published studies on the topic. Each one of these reviews concluded that the quality of evidence supporting its use was very low. This means that there is a strong possibility that the harms outweigh the benefits in the short term of several years. Discerning the long- term risks is scientifically difficult because in many regions over 95% of children go on to take cross-sex hormones within several years.

After your questions or concerns are addressed and you have decided to start or continue treatment with puberty blockers, you must sign this form in person with your prescribing physician.

What are other options are available for the treatment of minors with gender dysphoria?

Psychological therapy with a mental health care provider is an important option regardless of whether the individual undergoes medical treatment. Its purpose is to deal with significant degrees of anxiety, depression, self-harm, suicidality, eating disorder, school avoidance, and social anxiety that frequently accompanies gender dysphoria. Psychotherapy often involves the child separately and together with the parents. It attempts to overcome any developmental challenges the child has and to provide an opportunity for further maturation. Another option is follow-up of the child and parents at regular intervals without the employment of psychotherapy or puberty blockers. This recommendation is made because many studies have shown that the majority of children with gender dysphoria return to living in the gender that usually is seen in members of the child's sex by early adolescence if the child has not been socially transitioned prior to puberty. Those who have socially transitioned have a much lower detransition rate by early adolescence.

What are the different medications that are used to suppress puberty?

Puberty blockers are used to temporarily suspend or prevent the physical changes of puberty for minors. These medications block the signal from the pituitary gland in the brain to the internal sex organs—testes and ovaries that secret testosterone or estrogen.

Lupron and Histrelin are called gonadotrophn releasing hormone blockers (GnRH analogs) and effectively suppress numerous manifestations of puberty. Pediatric endocrinologists (children's doctors who specialize in hormones) use these medications to suppress puberty

in young children with premature (precocious) puberty, This use of GnRH analogues is approved by U.S. Food and Drug Administration (FDA). However, none of these medications have been approved by the FDA to be used in minors with gender dysphoria.

If a minor stops puberty suppression therapy, in a few months their body may restart the changes of puberty at the developmental stage they were before starting medication. However, some of effects of these medications may not be reversible.

What are the hoped-for changes associated with the use of puberty blockers?

- Delaying or suppressing puberty to relieve distress associated within incongruence between patient's current gender identity and biology.
- Providing time to reconsider whether to go further with cross-sex hormones or to desist and return to living according to my biological sex.

What are the potential side effects of the use of puberty suppression for treatment of gender dysphoria?

These side effects have been noted but their frequency varies considerably from patient to patient

- Injection site reactions such as pain, swelling, and abscess
- Weight gain
- Pain in the arms and legs or back
- Headache
- Acne or red, itchy rash and white scales (seborrhea)
- Serious skin rash (erythema multiforme)
- Stunting of growth in height
- Mood changes
- Swelling of vagina, vaginal bleeding, and vaginal discharge
- Upper stomach pain

- Diarrhea
- Bleeding
- Nausea and vomiting
- Fever
- Itching
- Ligament sprain
- Fracture
- Breast tenderness
- Difficulty sleeping
- Chest pain
- Excessive sweating

A major medical concern is a decrease in bone mineral density that may predispose to osteoporosis in the long term and fracture.

The effects of long-term puberty suppression therapy on cognitive and brain development are unknown. The social effects can be understood because peers will be undergoing the numerous changes in their feelings, anatomy, height while the puberty suppressed child remains looking more childlike. This can be expected to have psychological and social effects.

In the vast majority of cases, puberty suppression treatment for gender dysphoria is followed by the use of cross-sex hormones, such as estrogen or testosterone. This must be considered when starting puberty blockers because the child's personal identity as a trans person is likely to further solidify and the child anticipates subsequent hormonal and possibly surgical treatment. Thus, parents and their physician must discuss long term effects rather than simply side effects of puberty blockers alone. This fact, alone, makes the side effects of puberty blockers difficult to separate from the effects seen once cross-sex hormones are begun.

Many physicians have noted that sterility and the inability to have orgasm are far more common in those who underwent puberty suppression at the early stages of puberty.

For biological boys who begin puberty blockers early in puberty and who go on to take estrogenic compounds, the failure of the penis to grow as would be expected to occur in the early years of puberty, makes genital reconstruction of female appearing genitalia more complicated, necessitating the use of a piece of the colon rather than the penile skin. Thus, considering puberty blockers have long term effects that often do not seem highly relevant with a child between nine and twelve years of age.

What are the requirements to receive puberty suppression for gender dysphoria?

As minors as young as age 9 may be in early puberty, providing puberty blockers relies on parents' understanding the hoped-for benefits and social, psychological, mental, and medical risks. One cannot depend upon any minor's mental development to have acquired the ability to provide the legal standard for informed consent. Minors may be considered to assent to this treatment even if they cannot conceptual or weigh the consequences. The specific requirements for a minor to receive and continue treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders or International Classification of Diseases;
2. The professional and parental conclusion is that the cross-gender identification is likely to persist and be stable;
3. Puberty suppression has been recommended by a mental health professional and hormone prescribing professional;
4. The parents and child wish to avoid puberty for fear of mental decompensation.
5. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
6. 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.

7. Undergoes evaluation by the prescribing physician or their designated covering physician at least every 6 months;
8. Undergoes relevant laboratory testing at least every 6-12 months during pubertal suppression and for masculinizing therapy and every 3 months in the first year and then annually for feminizing therapy;
9. Undergoes X-rays of the hand (bone age) when clinically indicated;
10. Undergoes bone density scan (DEXA) when clinically indicated.
11. Undergoes continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

PARENTAL CONSENT:

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

1. The minor's prescribing physician has fully informed me about:
   a. the hoped-for benefits and risks of treatment with puberty blockers;
   b. the possible or likely consequences of treatment with puberty blockers and puberty suppression; and
   c. potential alternative treatments.
2. I have read and understand the information provided in this form.
3. I understand that I may decide to stop treatment at any time.
4. I agree to notify the prescribing physician if my child suffers from any side effects during treatment or am unhappy with the treatment

in any way, and if I have any concerns that the minor has worsening signs of depression or anxiety, is self-harming or is considering suicide.

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

6. I have had sufficient time and opportunity to discuss relevant treatment options with my minor's prescribing physician.

7. All my questions have been answered to my satisfaction by the minor's prescribing physician.

8. I know my child best and I acknowledge that I have sufficient information to provide informed consent for my minor to take, refuse, or postpone using puberty blocking medications.

9. I acknowledge that the professional team also has a good grasp of my child's development and current mental state.

10. 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.

My signature below attests to my consent for my minor to begin treatment for suppression of puberty.

_____

Parent/legal guardian's name (required)

_____ _____

Parent/legal guardian's signature (required) Date

_____

Parent/legal guardian's name (required)

_____ _____

Parent/legal guardian's signature (required) Date

PRESCRIBING PHYSICIAN SIGNATURE:

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

_____
Prescribing physician's name (required)

_____ _____
Prescribing physician's signature (required) Date

ASSENT OF MINOR:

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

_____
Minor's name (required)

_____ _____
Minor's signature (required) Date

WITNESS:

_____
Witness printed name

_____ _____
Witness signature Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

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

_____
Interpreter's printed name

_____ _____
Interpreter's signature Date

Feminizing Medications for Patients with Gender Dysphoria Patient Information and Informed Consent

Before you start treatment with hormones, you need to be aware of the hoped-for effects, expected side effects, and possible risks of using these medications. Similarly, before your minor child continues hormone treatment for gender dysphoria, both parents need to be aware of the expected effects and the unwanted risks of these drugs.

Your prescribing physician in consultation with you will decide the best medication regimen for you, keeping in mind your overall mental and physical health during the treatment process. The doctor will discuss with you all 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.

You should understand that medical treatment of people with gender dysphoria is based on years of experience but very limited well-designed research. Prospective data to verify its long-term medical and psychological safety are lacking. A well-known study published in January 2023 failed to demonstrate an overall mental health benefit for 16-year-old transgendered women followed for two years. The medications improved satisfaction with the patients' appearance, however. An older study also failed to demonstrate improved mental health with the use of hormones. Many short-term studies have suggested benefits. Since patients are expected to stay on their cross-sex hormone regimen for decades, short term studies are not highly reassuring in terms of medical and psychological consequences.

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

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

Hormonal treatment for gender dysphoria is referred to with many names: cross-sex hormones (CSH), gender affirming hormones (GAH), hormone replacement therapy (HRT). Such regimens require taking estrogen, as well as medicines to block the body from producing or utilizing testosterone. Use of these medications are "off label" because they have not been approved by the U.S. Food and Drug Administration (FDA) to treat gender dysphoria.

Different forms of estrogen are used to feminize a person's appearance. It can be given as an injection either weekly or every other week, as a pill taken once or twice a day, or as a skin patch that is changed weekly or more frequently.

Medications that block the production or effects of testosterone are called androgen blockers. Spironolactone, FDA approved as a diuretic, is the androgen blocker that is commonly used in the United States. In some cases, Bicalutamide is used to block the effects of testosterone, though it does not reduce testosterone levels. Bicalutamide (brand name Casodex), a prostate cancer drug, is rarely used in part because severe liver injury, known as fulminant and sometimes fatal hepatotoxicity has been recognized.

Various forms of progesterone may also be used by some physicians. This is a more medically controversial, however. 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 benefits of progesterone administration outweigh the potential risks. There is a theoretical risk of breast cancer associated with long-term exogenous progesterone.

You must be under the care of a licensed mental health care professional while using estrogens, antiandrogens, or androgen blockers because of their possible effect on mood. Your physical health needs to be monitored through blood studies and physician visits to maximize your continuing physical and mental health.

What are other options for the treatment of gender dysphoria?

Psychological therapy with a mental health care provider is an important option regardless of whether the individual undergoes medical treatment to deal with significant degrees of anxiety, depression, self-harm, suicidality, eating disorder, and substance dependence. Psychotherapy can be useful prior to considering hormonal treatment, during medical treatment, before or after surgical treatment to assist with the challenges of living as a trans person. Another option is watchful waiting without estrogen, to determine how your life unfolds without any intervention. As maturation proceeds some individuals no longer desire estrogen. Your physician will not be disappointed in you if you decide to postpone starting estrogen treatment.

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

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

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

1. The patient has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders or International Classification of Diseases;

2. Hormone therapy has been recommended by both a mental health professional and a hormonal prescribing professional after their independent assessments;
3. Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
4. The patient demonstrates the cognitive and maturational capacity to consent for hormone treatment. If you are a minor, your parents understand the medical and psychological risks and benefits and provide their consent;
5. The patient does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
6. The patient 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 which often is ultimately desired by individuals after taking hormones; and
7. The patient understands the effect of hormone treatment on reproduction and they have explored reproductive options;

The following may also be recommended by your prescribing physician:

1. An in-person evaluation by the prescribing physician or their designated covering physician every 3 months for the initial year and at least annually thereafter;
2. A suicide risk assessment by a licensed mental health care professional at least every 3 months for the initial year and at least annually thereafter;
3. Relevant laboratory testing;
4. Annual bone scans (DEXA) once a year for the first 5 years to allow monitoring of bone density (bone strength) during treatment;
5. Annual mental health assessments by a board-certified Florida licensed psychiatrist or psychologist;

6. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional; and
7. Continued monitoring by the prescribing physician for any side effects during treatment or referral to another physician or specialist for treatment.

What are the hoped-for effects of Feminizing Medications?

- Feminization of appearance;
- Happiness in expected body changes;
- Decreased distress over the incongruence between gender identify and biological sex; and
- Possible further consolidation of one's identity as a trans person.

What are the Side Effects of Feminizing Medications?

- Breasts will develop to reach their full size in two 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;
- Your body will make less testosterone, which may significantly reduce your sex drive;
- Your penis may never fully develop, particularly if you previously took puberty blockers;
- If you did not take puberty blockers, your penis and testes are likely to shrink;
- You will have fewer spontaneous erections;
- You may have less sexual desire, less firm erections and you may be unable to sustain an erection or penetration;
- Your sperm may no longer be fertile; infertility may be permanent even if treatment is discontinued, the risk of which is increased you

took puberty blockers prior to starting feminizing medication; and
- Conversely, it is possible that your sperm could still mature while taking feminizing medications and you may cause someone to get pregnant.

What are the Risks of Taking Estrogen?

Estrogen **SHOULD NOT** be used by anyone who has:
- Any estrogen-dependent cancer; or
- 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 migraine headaches;
- Has any seizure disorder;
- Is obese; or
- Smokes cigarettes or uses tobacco products.

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; and
- Stroke, which may cause permanent brain damage or death.

Please note that 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.

Other risks associated with taking estrogen include:

- Increased 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;
- Raised blood pressure, which increases the risk of heart attack and stroke;
- Increased risk of gallstones (stones in the gallbladder) and the need for gall bladder surgery (therefore please report any long- term abdominal pain you experience while taking estrogen to your prescribing physician);
- Increased risk of elevated prolactin levels and prolactinomas, which are non-cancerous tumors of the pituitary gland that can damage vision and cause headaches if not treated properly (therefore please report to your prescribing physician any changes in your vision, the occurrence of severe headaches, or any milky nipple discharge);
- Nausea and vomiting (please report to your prescribing physician any long-term nausea or vomiting);
- Migraines or can make them worse if you already have them;
- Hot flashes;
- Fatigue and difficulty focusing; and
- Excessive emotionality and depression.

Risks of Androgen Blockers and Antiandrogens (Spironolactone and Bicalutamide)

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

- Increase frequency and amount of urination;
- Increase thirst; and
- 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; and
  - Shortness of breath.

Taking Bicalutamide may cause numerous side effects which should be reported to your prescribing physician, including:

- Hot flashes or flushing;
- Bone, back, joint, or pelvic pain;
- Muscle weakness;
- Headaches;
- Respiratory symptoms such as shortness of breath, chest pain, and cough;
- Elevated blood pressure;
- Swelling of the hands, feet, ankles, or lower legs;
- Stomach and intestinal symptoms;
- 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;
- Urinary symptoms;
- Painful or swollen breasts;
- Yellowing of the skin or eyes;

- Extreme tiredness;
- Unusual bleeding or bruising;
- Lack of energy; and
- Flu-like symptoms.

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;
   c. potential alternative treatments; and
   d. the need to take my time without rushing into the treatment.

2. I have read and understand the information provided above.

3. I understand that I may decide to stop treatment at any time.

=

4. 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 want to harm myself or attempt suicide.

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

6. I have had sufficient time and opportunity to discuss relevant treatment options with the prescribing physician.

7. All my questions have been answered to my satisfaction by the prescribing physician.

8. I know enough to give informed consent for me to take, refuse, or postpone taking feminizing medications.

9. 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.

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

FOR ADULTS _____ **(OVER 18 YEARS OLD)**
Date of birth

_____
Patient's printed name (required)

_____ _____
Patient's signature (required) Date:

FOR MINORS CONTINUING WITH HORMONE TREATMENT:

_____
Printed name of parent or legal guardian(required)

_____
Signature of parent or legal guardian(required) Date:

PRESCRIBING PHYSICIAN:

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

_____
Prescribing physician's printed name (required)

_____ _____
Prescribing physician's signature (required) Date

WITNESS:

_____
Witness' printed name (required)

_____ _____
Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

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

_____

Interpreter's printed name

_____ _____

Interpreter's signature Date

Masculinizing Medications for Patients with Gender Dysphoria
Patient Information and Informed Consent

Before you start or continue treatment with hormones, you need to be aware of the hoped-for benefits, expected side effects and possible risks of using these medications. Similarly, before your minor child continues on hormone treatment for gender dysphoria, both parents need to be aware of the expected effects and the unwanted risks of these drugs.

Medical treatment of people with gender dysphoria has long been employed but is based on low-quality evidence. It is not based on the high scientific standard of controlled studies, adequate long-term follow up of patient groups. Follow-up outcome studies are few, short-term, and have yielded contradictory group results and varied individual patient results. Testosterone can masculinize appearance, but there is controversy and uncertainty regarding the long-term physical and mental health of minors that are treated with hormones for this purpose.

Your doctor, in consultation with you and other medical professionals, will decide what medications are best for you, keeping in mind your overall physical and mental health before and during the gender transition process. Your doctor will talk with you about the effects and possible risks associated with the use of these medications. It is your responsibility, however, to read and understand the following information and to raise questions with your doctor. We encourage you to weigh the hoped-for benefits, known side effects, and long term medical and social risks repeatedly, rather in one sitting.

Every medication, including those for gender dysphoria, has short- and long-term risks, benefits, and predictable side effects. It is important to understand each of these before undergoing or continuing with hormone treatment. Your willingness to consent to this treatment obligates you monitor your (or your minor child's) health with laboratory studies and regular visits to the prescribing doctor. This is necessary to recognize

early on and to modify your risks of harm.

After your questions or concerns are addressed and you have decided to consent to hormone treatment, you will need to sign this form.

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

Hormonal treatment for gender dysphoria is referred to with many names: cross-sex hormones (CSH), gender affirming hormones (GAH), hormone replacement therapy (HRT). Such regimens require taking testosterone in various forms. Use of these medications are "off label" because they have not been approved by the U.S. Food and Drug Administration (FDA) to treat gender dysphoria.

How is testosterone taken?

Testosterone is usually injected every one to four weeks, but it can also be given as a gel or a patch. It is rarely given as a pill because the body does not absorb it properly, and it has been known to cause potentially fatal liver disease. 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). Testosterone levels fluctuate based on the amount and frequency of injections. Testosterone can cause several types of negative mood states—depression, irritability, aggressiveness. These powerful medically-induced mood regulation changes are the reason individuals must be under the care of a licensed mental health care professional.

What are other options for the treatment of gender dysphoria?

Psychological therapy with a mental health care provider is an important option regardless of whether the individual undergoes medical treatment to deal with significant degrees of anxiety, depression, self-harm, suicidality, eating disorder, and substance dependence. Psychotherapy

can be useful prior to considering hormonal treatment, during medical treatment, before or after surgical treatment to assist with the challenges of living as a trans person. Another option is watchful waiting without testosterone, to determine how your life unfolds without any intervention. As maturation proceeds some individuals no longer desire testosterone. Your physician will not be disappointed in you if you decide to postpone starting testosterone treatment.

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 hormonal therapy. If these requirements are not met, the hormone may be discontinued by the prescribing physician.

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

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. Hormone therapy has been recommended by both a mental health professional and a hormonal prescribing professional after their independent assessments;
3. Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
4. The patient demonstrates cognitive and maturational capacity to consent for the specific gender dysphoria hormone treatment;
5. The patient does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
6. The patient demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of the recommended

hormonal regimen as well as the medical, social psychological risks and benefits; and

7. The patient understands the effect of hormone treatment on reproduction and has explored reproductive options.

The following may also be recommended by your doctor:

1. An in-person evaluation by the prescribing physician or their designated covering physician every 3 months for the initial year and at least annually thereafter;
2. A suicide risk assessment by a licensed mental health care professional at least every 3 months for the initial year and at least annually thereafter;
3. Relevant laboratory testing;
4. Annual bone scans (DEXA) once a year for the first 5 years to allow monitoring of bone density (bone strength) during treatment;
5. Annual mental health assessments by a board-certified Florida licensed psychiatrist or psychologist;
6. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional; and
7. Continued monitoring by the prescribing physician for any side effects during treatment or referral to another physician or specialist for treatment.

Risks of Testosterone

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

- Is pregnant;
- Has coronary artery disease as it could increase your risk for a fatal heart attack; or
- Has a history of perpetrating violence.

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; or
- Smokes cigarettes.

Taking more testosterone than prescribed:

- 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.
-

Summary of Testosterone Benefits and Risks

HOPED-FOR BENEFITS	RISKS
• Appear more like a man • Happiness in expected body changes; • Decreased distress from the incongruence between gender identity and biological sex; • Possible further consolidation of one's identity as a trans person; • More physical energy • More sex drive • Reduced or absent menstrual periods	• Acne** • Blood clots (with risk significantly increased by smoking) • Bigger hypersensitive clitoris* • Mood changes, for example, more aggression • Hair loss at the temples and crown of the head and the possibility of being completely bald* • 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 • Migraines • More abdominal fat — redistributed to a male shape** • Risk of heart disease • Swelling of hands, feet, and legs • Vaginal atrophy (dryness, tearing, bleeding, pain, infection, and painful intercourse) ** • Weight gain

* These changes are likely to be permanent even if testosterone is discontinued

** These changes could be permanent, but may improve if you stop taking testosterone.

CONSENT:

My signature below confirms that:

My prescribing physician has talked with me about:

1. The benefits and risks of taking testosterone;
2. The possible or likely consequences of hormone therapy; and potential alternative treatments.
3. I have read and understand the information provided above.
4. I understand that I may decide to stop treatment at any time.
5. 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 want to harm myself or attempt suicide.
6. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with testosterone. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.
7. I have had sufficient time and opportunity to discuss relevant treatment options with my prescribing physician. My physician has urged me to take my time in considering this hormonal option.
8. All my questions have been answered to my satisfaction by my prescribing physician.
9. I know enough to give informed consent to take, refuse, or postpone taking testosterone.
10. 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.

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

FOR ADULTS _____ **(OVER 18 YEARS OLD)**
Date of birth

_____
Patient's printed name (required)

_____ _____
Patient's signature (required) Date:

FOR MINORS CONTINUING WITH HORMONE TREATMENT:

_____
Printed name of parent or legal guardian(required)

_____
Signature of parent or legal guardian(required) Date:

PRESCRIBING PHYSICIAN:

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

_____
Prescribing physician's printed name (required)

_____ _____
Prescribing physician's signature (required) Date

WITNESS:

_____
Witness' printed name (required)

_____ _____
Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

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

_____

Interpreter's printed name

_____ _____

Interpreter's signature Date