

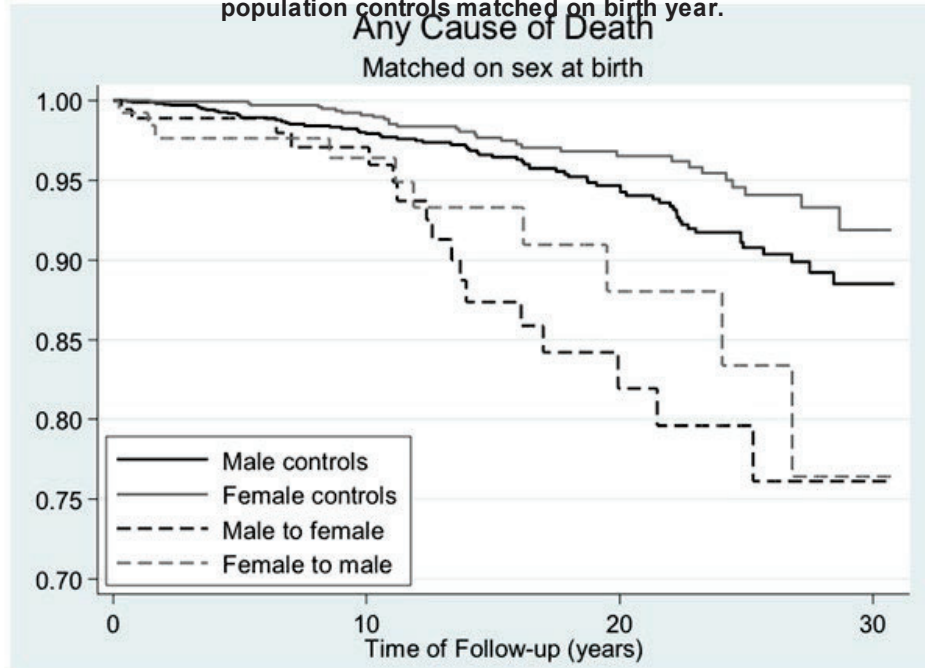
8. Health Concerns (62%)
  9. Transition Failed to Help with Dysphoria (50%)
  10. Found Other Ways to manage Dysphoria (45%)
  11. Unhappiness with Social Changes (44%)
  12. Change in Political Views (43%)
- iv. As many as 60% of detransitioners requested psychological support to deal with the consequences of their regret
- XI. Among long term studies in adults after surgical and medical treatment of gender dysphoria it took about 10 years for regret to develop and similarly there were differences in mortality when compared to the general population that were not seen until about 10 years after surgical treatment in adults. (See Figure 1).
- XII. It is not known whether detransition can be prevented or whether inappropriate transition can be avoided with current knowledge. The current model is affirmation without question, and this will likely lead to harm for as many as ~33% of you with these therapies.
- XIII. Medical Complications and Side Effects in Children and Adolescents:
- a. Fertility: Treating youth with puberty blockers will temporarily impair your ability to make sperm or mature eggs for future fertility. In other words, by taking these therapies, you may be unable or have difficulty in having your own biological children one day. Going through later puberty could help with fertility but this will also lead to what may be for you unwanted secondary sexual characteristics.
    - i. It may take 0.7 to 3 years after stopping puberty blockers for boys to produce sperm. Further, as stated earlier almost all children who start puberty blockers will proceed to cross sex hormones and estrogen treatment will impact sperm production as well.
    - ii. There are no studies looking at ovarian function after puberty blockers are stopped in girls.
    - iii. There is an increased risk of polycystic ovarian syndrome in transgender males both prior to and because of testosterone treatment.
    - iv. It is much harder to preserve eggs than sperm for later use in reproduction.
    - v. It is thought that earlier use of puberty blockers may help with the physical appearance after transition, but the data is of very low quality in this regard and may not outweigh the side effects.
  - b. Bone Health: Adverse effects on bone mineralization are seen with GnRH agonists and they also effect the rates your bones increase their minerals. We know that about 30% of your bone mineralization happens during puberty and using puberty blockers may slow this leading to osteoporosis in later life.

- i. Cross Sex Hormone treatment for about 5.8 years did not appear to completely reverse these differences on bone mineral density or accrual.
    - ii. Treating adults with puberty blockers also negatively impacts bone density.
    - iii. **Physical Activity, calcium supplementation and vitamin D supplementation may help if you are on these treatments to help protect your bone health.**
  - c. BMI and Body Mass: BMI will not likely change though weight gain is reported in studies using puberty blockers for other reasons. Fat Mass will increase in your body and muscle mass may decrease while only using puberty blockers.
  - d. Arterial Hypertension: This has been seen in adults and children medically treated for gender dysphoria. Elevated blood pressure is a major risk factor increasing the chance of a stroke or a heart attack in later life.
  - e. Hot flashes, fatigue and mood alterations: These are likely to occur with isolated puberty suppression.
  - f. Required Monitoring Children Puberty Blockers: Height, Weight, Sitting Height, Blood pressure and Tanner Staging every 3 months. Every 6-month labs include LH, FSH, Estradiol/Testosterone, Vitamin D. Yearly Bone Age until growth plates are fused and yearly bone density by DEXA scan of the spine and whole body.
  - g. Required Monitoring Children Puberty Induction: Every 3 months height, weight, sitting height, blood pressure and Tanner staging. Every 6 months in transgender males: CBC, Lipids, Testosterone, Vitamin D. In transgender females every 6 months: prolactin, estradiol, Vitamin D. Yearly bone mineral density in all children and adults until 30 years of age of the lumbar spine, hip and whole body.
- XIV. A table of potential side effects in children with gender dysphoria and incongruence is noted in Table 2:
- XV. All legal guardians need to sign informed consent for children and separate assent from the child as well.

**Table 2 Potential, Known and Theoretical Risks Unique to Children & Adolescents with Gender Dysphoria related to GnRH agonists, Cross-Sex Hormones and Other Hormone Related Antagonist Treatments**

<b>Treatment Related Side-Effects</b>	<b>Potential Treatment Related Outcomes</b>
Decreased Bone Mineral Density	Osteoporosis and Fractures
Decreased Linear Growth	Short Stature
Compromised Fertility	Inability to Have Your Own Biological Children
Primary Hypogonadism	Testicular or Ovarian Failure
Abnormal Brain Development	Differences Related to Your Functioning with Peers at work and school
Decreased Cognitive Function	School & Career Challenges
Increased Fat Mass	Obesity
Decreased Lean Body Mass	Obesity and Increased Diabetes Risk
Arterial Hypertension	Increased Risk of Stroke and Heart Attack, greater risk if smoking
Dyslipidemia	Increased Risk of Stroke and Heart Attack, greater risk if smoking
Arterial Hypertension	Increased Risk of Stroke and Heart Attack, greater risk if smoking
Hot Flashes/Fatigue/Mood Alterations	Inability to work and hold a job or go to school.
Milky breast discharge or breast cancer (transfemales)	Get prolactin measured. Breast cancer is very rare in young people.
Fat changes	Distribution of your fat will change with testosterone and estrogen discuss with your physician
Vaginal Atrophy (transmales with testosterone)	Lead to your cervix and vagina becoming fragile leading to tears or abrasions, pelvic infections, and increased risk of sexually transmitted disease if you have vaginal sex. Painful intercourse is often seen with vaginal atrophy.
Sperm will not mature, decrease in erections, penetrative sex difficult, testicles shrink by 25-50%, less interest in sex.	These are seen in transfemales.
Migraine Headaches	Seen with estrogen or testosterone treatment talk with your physician if you start getting bad headaches.
Emotional Changes (with estrogen or testosterone treatment)	Stay in touch with your psychotherapist as you may get irritable, more easily frustrated, angry, think about killing yourself or even committing suicide (see Figure 4 attached)
Decreased Bone Mineral Accrual	Increased Pain with Spinal and Long Bone Fractures in early adulthood as opposed to elderly years in the general population

**Figure 1. Death from any cause as a function of time after sex reassignment among 324 transsexual persons in Sweden (male-to-female: N = 191, female-to-male: N = 133), and population controls matched on birth year.**



Dhejne C, Lichtenstein P, Boman M, Johansson ALV, Långström N, et al. (2011) Long Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden. PLOS ONE 6(2): e16885. <https://doi.org/10.1371/journal.pone.0016885> <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0016885>

**(Figure 2)**

*The* NEW ENGLAND JOURNAL *of* MEDICINE

ORIGINAL ARTICLE

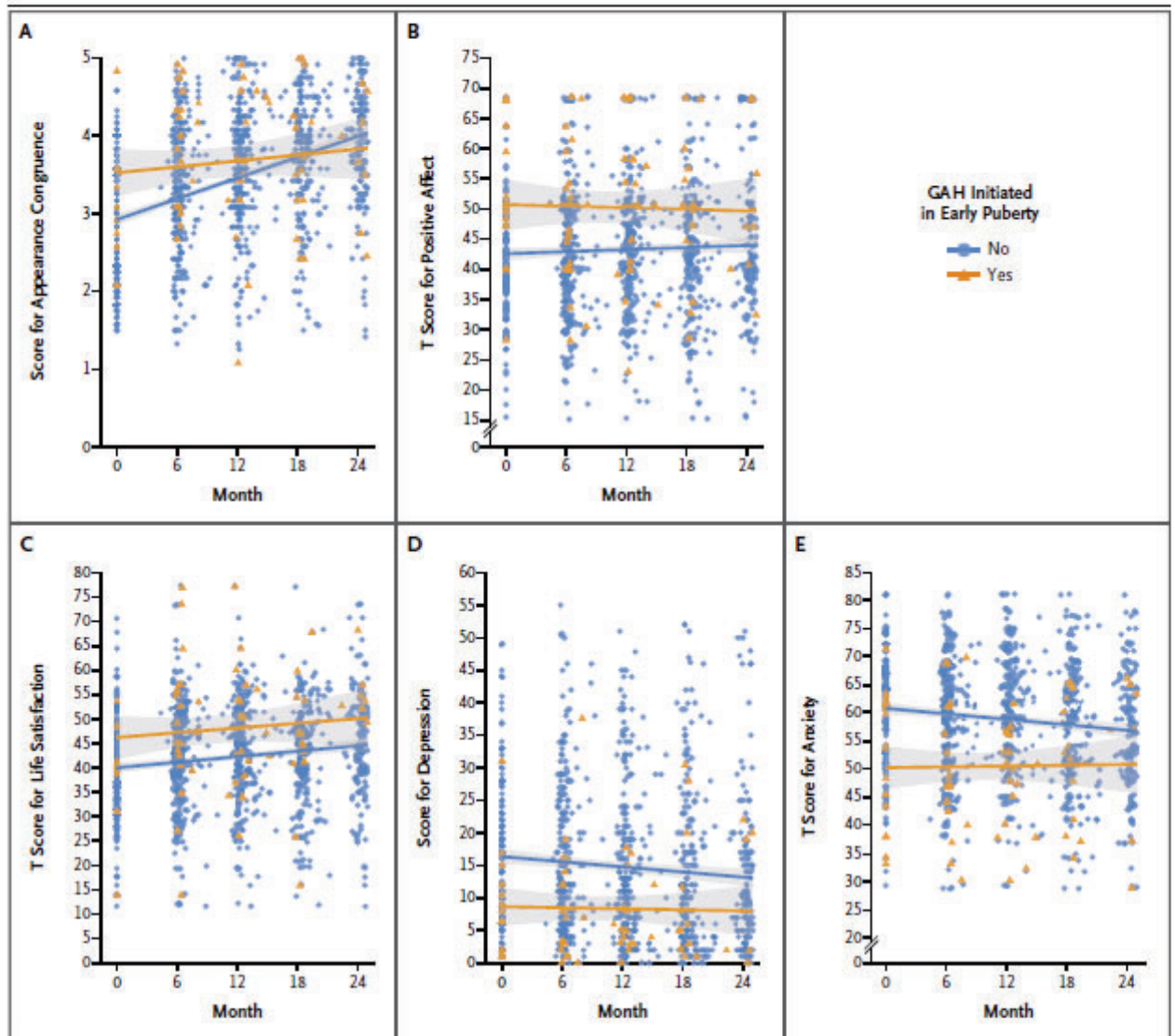
## Psychosocial Functioning in Transgender Youth after 2 Years of Hormones

Diane Chen, Ph.D., Johnny Berona, Ph.D., Yee-Ming Chan, M.D., Ph.D.,  
Diane Ehrensaft, Ph.D., Robert Garofalo, M.D., M.P.H., Marco A. Hidalgo, Ph.D.,  
Stephen M. Rosenthal, M.D., Amy C. Tishelman, Ph.D.,  
and Johanna Olson-Kennedy, M.D.

ABSTRACT

Figure 3):

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**Figure 2. Psychosocial Outcomes during 2 Years of GAH.**

Shown are changes in participant-reported measures over a period of 2 years of treatment with gender-affirming hormones (GAH). Scores on the Appearance Congruence subscale of the Transgender Congruence Scale (Panel A) range from 1 to 5, with higher scores indicating greater appearance congruence. T scores for the Positive Affect measure from the NIH (National Institutes of Health) Toolbox Emotion Battery (Panel B) range from 0 to 100, with higher scores indicating greater positive affect. T scores for the Life Satisfaction measure from the NIH Toolbox Emotion Battery (Panel C) range from 0 to 100, with higher scores indicating greater life satisfaction. Scores on the Beck Depression Inventory-II (Panel D) range from 0 to 63, with higher scores indicating greater depression. T scores on the Revised Children's Manifest Anxiety Scale (Second Edition) (Panel E), range from 0 to 100, with higher scores indicating greater anxiety. Individual scores are depicted with orange triangles for youth initiating GAH in early puberty ("Yes") and with blue circles for youth who did not initiate GAH in early puberty ("No"). Lines indicate mean scores for each group, with gray shaded bands for 95% confidence intervals.

**Figure 4)**

PSYCHOSOCIAL FUNCTIONING IN TRANSGENDER YOUTH

<b>Table 2. Adverse Events.</b>	
<b>Event</b>	<b>No. of Events in Sample</b>
Any event	15
Death by suicide	2
Suicidal ideation reported during study visit	11
Severe anxiety triggered by study visit	2

*Effects of Racial and Ethnic Identity*

At baseline, youth of color had higher scores for appearance congruence, lower scores for de-

instruments. Our findings were similar to those of other longitudinal studies of transgender and nontransgender youth with GAH, which showed reductions in depression and anxiety<sup>6</sup> and increases in self-esteem with small-to-moderate effect sizes over a period of up to 1 year. We also found findings in a larger sample of transgender and nontransgender youth from four geographic locations in the United States and found similar findings over a period of 2

Increasing appearance congruence is a primary goal of GAH, and v

Physician Name:	License Number:	Date of Signature:
Patient Name:	DOB:	Date of Assent:
Parent Guardian Name 1:	Signature:	Date of Signature:
Parent Guardian Name 2:	Signature:	Date of Signature:

## **Feminizing Medications for Patients with Gender Dysphoria**

### **Patient Information and Informed Consent and Assent for Minors**

Before starting or continuing medications to transition your adolescent to their affirmed gender, you need to be aware of the effects and possible risks of these medications.

After your questions or concerns are addressed and you have decided to start or continue medications for your child, a parent/legal guardian and your child will need to initial the statements of this form as well as sign the consent form. Both the parent/legal guardian and your child will need to sign in person. If there is more than one parent/legal guardian, both will have to sign. The second parent or guardian can give verbal content via video (by presenting photo ID) or by notarized document. Your child will also need to assent this form.

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

Part of transition for many transgender people involves taking hormones, this is also called hormone replacement therapy or HRT. HRT in transgender girls and women means taking estrogens (female hormones), as well as medicines to block their body from producing or utilizing testosterone (male hormones). Use of these medications in adolescents with gender dysphoria, is considered if specific criteria listed below is met, but these medications do not have the FDA indication to be used in this population, in other words, it is "off label use".

Different forms of the hormone estrogen are used to feminize appearance in transgender females. Estrogen can be given as an injection to be given weekly or every other week, as a pill to be taken daily or twice a day, or as a patch to be changed weekly or every three or four days. Medications that block the production or effects of testosterone are called androgen blockers. Androgen is another term for male sex hormones. Spironolactone is the androgen blocker that is most commonly used in the United States. Other medicines are sometimes used, but because spironolactone is relatively safe, inexpensive, and effective to block testosterone, it is the primary androgen blocker used for transgender girls. In some cases, Bicalutamide is a cancer treatment drug and is also known by its brand name, Casodex. It is approved for the treatment for prostate cancer. Bicalutamide belongs to the group of medicines called antiandrogens. It works by blocking the effects of testosterone (a male hormone), which helps stop the growth and spread of cancer cells. Bicalutamide blocks the effects of testosterone, but does not reduce testosterone levels.

Every medication has risks, benefits, and side effects that are important to understand before starting or continuing treatment. The effects and side effects of medicines used for transition need to be monitored with laboratory studies and regular visits to your child's provider, to make sure that there are no negative medical and mental health effects.



Both these medicines, as well as the process of transitioning can affect your adolescents' mood. It is important that your child is under the care of a gender-qualified therapist while undergoing transition. The therapist can work with your child, your family and friends and your school staff.

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

The other option available is psychological therapy with a mental health provider that has experience in treating youth with gender dysphoria. We recommend this regardless of whether your child undergoes suppression of puberty or not, due to the high risk of anxiety, depression, self-harm and even suicide.

**What are the requirements to receive hormone replacement therapy (HRT) in our program?**

In order to receive hormone replacement therapy (HRT), there are specific requirements that need to be met before and during the treatment. These requirements will allow us to monitor your child's medical as well as mental health wellbeing during HRT. If these requirements are not met, HRT may be discontinued in the best interest and safety of your child.

Before beginning or continuing HRT your child needs to undergo a thorough psychological and social evaluation performed by a licensed psychiatrist or psychologist. We also require your child has participated in at least 6 months of psychological therapy. We will need a letter from your child's therapist confirming this as well as a letter from the a licensed psychiatrist or psychologist.

After all this has taken place, HRT can be initiated or continued if your child meets the criteria, which includes ALL of the following:

1. Fulfill the current DSM or ICD criteria for gender dysphoria or transsexualism.
2. Have pubertal changes that have resulted in an increase in gender dysphoria.
3. Do not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment.
4. Have adequate psychological and social support during treatment.
5. Have experienced puberty to at least Tanner stage 2 (first stage of puberty)
6. Demonstrate knowledge and understanding of the expected outcomes of HRT, as well as the medical and social risks and benefits of sex reassignment.

AND EITHER:

7. Your child is  $\geq 16$  years old and has experienced a full social transition to the desired gender for  $\geq 2$  year.

OR

8. Your child is 14-15 years of age, has experienced a full social transition to the desired gender for  $\geq 4$  years.

After HRT has been initiated, the following will be required:

1. Visits with the endocrinologist or adolescent medicine physician every 3 months.
2. Suicide risk assessment performed during each clinic visit every 3 months.
3. Laboratory testing every 3-6 months.
4. X ray of the hand (bone age) once a year if your child is still growing.
5. Bone mineral density scan (DXA) once a year: this will allow us to monitor your child's bone density (bone strength) during treatment, which can be altered by HRT.
6. Yearly mental health assessments by a licensed psychiatrist or psychologist. This will allow us to monitor your child's psychological wellbeing and adjustment while on HRT.
7. Continued counseling with a therapist during the treatment period, with the frequency recommended by the therapist.

**Please initial each statement on this form** to show that you understand the benefits, risks, and changes that may occur from giving these medications to your child.

### Effects of Feminizing Medications

\_\_\_\_\_ I know that estrogen, anti-androgens, or both may be prescribed to feminize my adolescent's appearance.

\_\_\_\_\_ I know it can take several months or longer for the effects to become noticeable. I know that no one can predict how fast – or how much – change will happen.

\_\_\_\_\_ I know that taking estrogen will cause the following changes in my adolescent's breasts:

- Will develop breasts.
- It takes several years for breasts to get to their full size.
- The breasts will remain, even if estrogen is stopped.
- A milky discharge from the nipples may appear. If this happens, this should be checked by my adolescent's provider. It could be caused by the estrogen or by something else.

- The risk of breast cancer can be increased to as high as if your adolescent had been born female.

\_\_\_\_\_ I know that the following changes may or may not occur if the medicines are stopped:

- If body hair is present, it will become less noticeable and will grow more slowly although it won't stop completely, even after taking medicines for years.
- There might be less fat on the abdomen and more on the buttocks, hips, and thighs. The fat will be redistributed to a more female shape — changing from —apple shape to —pear shape.
- Your child will lose muscle and strength in the upper body.
- The skin may become softer.

\_\_\_\_\_ I know that my adolescent's body will make less testosterone. This may affect sex life in different ways and the future ability to cause a pregnancy:

- The testicles may shrink.
- The penis may never fully develop if previously on a puberty blocker.
- There will be fewer spontaneous erections.
- Sperm may no longer get to mature. This could makes your adolescent less likely to cause a pregnancy while taking hormones and may be a permanent change even hormone therapy is discontinued.
- There is a risk your child will never produce mature sperm again and this risk is further increased if your child took puberty suppressing hormones (“puberty blockers”), prior to starting feminizing medications. However, it is also possible that the sperm could still mature even while taking hormones. So, I know that my adolescent may get someone pregnant.
- The options for sperm banking have been explained.

\_\_\_\_\_ I know that some parts of the body will not change much by using these medicines.

- If present, the hair of the beard and moustache may grow more slowly than before. It may become less noticeable, but it will not go away.
- If your child went through a “male puberty” and has a “male voice”, the pitch of the voice will not rise, and the speech patterns will not become more like a woman's.
- If present, the “Adam's apple” will not shrink.

\_\_\_\_\_ **I know that there can be mood changes with these medicines. I agree to have my adolescent continue therapy with a qualified therapist.**

\_\_\_\_\_ I know that using these medicines to feminize is an off-label use. This means it is not approved by the Food and Drug Administration (FDA). I know that the medicine and dose that is recommended is based on the judgment and experience of my adolescent's health care provider and there is no data in the medical literature or controlled research studies that supports the timing, dosing and type of administration of HRT.

### **Risks of Feminizing Medications**

Estrogen should not be used by anyone who has a history of

- An estrogen-dependent cancer
- A 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 followed by a specialist)

Estrogen should be used with caution and only after a full discussion of risks by anyone with:

- strong family history of breast cancer or other cancers that grow quicker when estrogens are present
- diabetes
- heart disease
- chronic hepatitis or other liver disease
- high cholesterol
- migraines or seizures
- obesity
- cigarettes/nicotine use

\_\_\_\_\_ I know that the side effects and safety of these medicines are not completely known. There may be long-term risks that are not yet known.

\_\_\_\_\_ **I realize that this treatment will not prevent serious psychiatric events such as a suicidal attempt.**

\_\_\_\_\_ I know that my child should not take more medicine than prescribed.

Taking too much medication:

- Will increase health risks
- Won't make changes happen more quickly or more significantly.

\_\_\_\_\_ I know these medicines can damage the liver and may lead to liver disease. Therefore, I should be checked for possible liver damage as long as my child takes them.

\_\_\_\_\_ I know these medicines cause changes that other people will notice. Some transgender people have experienced discrimination. I know my child's clinician can help me find support resources.

## Risks of Estrogen

\_\_\_\_\_ I know that taking estrogen increases the risk of blood clots or 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 damage or death.
- Pulmonary embolism - blood clot to the lungs- which may cause permanent lung damage or death
- Stroke, which may cause permanent brain damage or death.

\_\_\_\_\_ I know that the risk of blood clots is much worse if my child smokes cigarettes. The danger is so high that your child should stop smoking completely if estrogen is started.

\_\_\_\_\_ I know taking estrogen can increase the deposits of fat around internal organs. This can increase the risk for diabetes (blood sugar problems) and heart disease. Both of these disorders further increase the risk of heart attack and stroke.

\_\_\_\_\_ I know taking estrogen can raise blood pressure which also further increase the risk of heart attack and stroke.

\_\_\_\_\_ I know that taking estrogen increases the risk of gallstones (stones in the gallbladder), and I will talk our child's physician if severe or long-lasting pain in the abdomen occurs.

\_\_\_\_\_ I know that estrogen can cause nausea and vomiting, and I should talk with our child's clinician if long-lasting nausea or vomiting occurs.

\_\_\_\_\_ I know that estrogen can cause migraines or make them worse if your child already has them.

\_\_\_\_\_ I know that estrogen can cause hot flahes

\_\_\_\_\_ I know that estrogen can cause my child to feel tired or have difficulty in focusing.

\_\_\_\_\_ I know taking estrogen increases the risk of elevated prolactin level and/or a prolactinomas. These are non-cancerous tumors of the pituitary gland. I know they are not usually life threatening, but they can damage vision and cause headaches if they are not treated properly. Therefore, if my child has changes in vision, headaches that are worse when waking up in the morning, and/or a milky discharge from the nipples, these can be signs of a prolactinoma, and I will talk to my child's

provider. There is a blood test that can check for this.

**Risks of Androgen Antagonists (spironolactone and/or bicalutamide)**

\_\_\_\_\_ I know that spironolactone affects the balance of water and salt balance in the kidneys. This may:

- Increase the amount of urine produced, making it necessary to urinate more frequently.
- Increase thirst.
- Increase risk of dehydration (not having enough water), and your child should make sure to drink plenty of water. If your child is peeing less than usual or have dark, strong smelling pee, feel thirsty or feel dizzy or light-headed – these can be signs of dehydration.

\_\_\_\_\_ I know that spironolactone affects the balance of potassium balance in the kidneys. This may cause high levels of potassium which:

- Can cause changes in heart rhythms that may be life threatening.
- Reduce blood pressure or cause low blood pressure which can cause fatigue, lightheadedness
- tingling feeling
- muscle weakness
- shortness of breath

\_\_\_\_\_ I understand that my child's doctor will perform a blood test to monitor this risk while on the medication.

\_\_\_\_\_ I know that bicalutamide may cause side effects. I agree to contact my child's physician if my child is experiencing:

- hot flashes or flushing
- bone, back, or pelvic pain
- muscle weakness
- muscle or joint pain
- headache
- shortness of breath
- increased blood pressure
- swelling of the hands, feet, ankles, or lower legs
- cough
- constipation
- nausea
- vomiting
- abdominal pain
- diarrhea
- gas

- change 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 stomach
- extreme tiredness
- unusual bleeding or bruising
- lack of energy
- upset stomach
- loss of appetite
- flu-like symptoms
- dull or sharp side pain
- chest pain

### **Requirements of Treatment with HRT**

\_\_\_\_\_ I understand and agree with all the requirements explained above, in order to receive HRT.

\_\_\_\_\_ I know that the mental health team and/or treating physician may recommend to stop treatment because it no longer outweighs the risks, there is insufficient social or psychological support, or our program requirements to treat are not met.

\_\_\_\_\_ I know 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 know that I or my child can change our mind and decide to stop treatment at any time.

\_\_\_\_\_ I agree to tell my physician if I think my child has any problems or is unhappy with the treatment.

\_\_\_\_\_ I know that after my child turns 18, medical care will have to be transitioned to an adult endocrinologist or physician.

### **Prevention of Complications while under Treatment of HRT**

\_\_\_\_\_ 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 themselves or attempt suicide.**

\_\_\_\_\_ I know my child needs periodic medical evaluations clinic to make sure that my child is responding appropriately. This includes clinic visits with the pediatric endocrinologist or adolescent medicine 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.

\_\_\_\_\_ I understand that my physician will be required to monitor for side effects and that my child may have to be referred to another specialist if complications. I agree to take my child to those specialists as recommended.

\_\_\_\_\_ I understand that my physician will be required to continue to provide care in the event I may not have the ability to pay for visits.

\_\_\_\_\_ I understand if my child no longer meets criteria for treatment, has significant side effects that the physician or specialist feel that treatment must stopped, or my child wishes to discontinue treatment, the physician will continue to provide care through the detransition



**Our signatures below confirm that:**

- My clinician has talked with me and my child about:
  - The benefits and risks of taking feminizing medication
  - The possible or likely consequences of hormone therapy
  - 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 of risks.
- I have had enough opportunity to discuss treatment options with our child’s clinician.
- My child is in agreement with this treatment and the signature of my child on the assent form attests to this agreement.
- All of my questions have been answered to my satisfaction.
- I believe I know enough to give informed consent to take, refuse, or postpone therapy for my adolescent child with feminizing medications.

**Based on all this information:**

\_\_\_\_\_ I want my adolescent child to begin taking estrogen.

\_\_\_\_\_ I want my adolescent child to begin taking androgen antagonists (e.g., spironolactone).

\_\_\_\_\_ I do not wish my adolescent child to begin taking feminizing medication at this time.

\_\_\_\_\_  
Parent or legal guardian’s name

\_\_\_\_\_  
Parent or legal guardian’s signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Parent or legal guardian’s name

\_\_\_\_\_  
Parent or legal guardian’s signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Prescribing clinician's name

\_\_\_\_\_  
Prescribing clinician's signature

\_\_\_\_\_  
Date

**ASSENT OF A MINOR:**

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

\_\_\_\_\_  
Minor's name (printed)

\_\_\_\_\_  
Minor's signature

\_\_\_\_\_  
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 Name (Print)

\_\_\_\_\_  
Interpreter's signature

\_\_\_\_\_  
Date





**Testosterone Treatment for Patients with Gender Dysphoria**  
**Patient Information and Informed Consent and Assent for Minors**

Before starting or continuing medications to transition your adolescent to their affirmed gender, you need to be aware of the effects and possible risks of these medications.

After your questions or concerns are addressed and you have decided to start or continue medications for your child, a parent/legal guardian and your child will need to initial the statements of this form as well as sign the consent form. Both the parent/legal guardian and your child will need to sign in person. If there is more than one parent/legal guardian, both will have to sign. The second parent or guardian can give verbal content via video (by presenting photo ID) or by notarized document. Your child will also need to assent this form.

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

Part of transition for many transgender people involves taking hormones, this is also called hormone replacement therapy or HRT. HRT in transgender males means taking testosterone. This is the sex hormone that makes certain features appear typically male. It builds muscle and causes the development of facial hair and a deeper voice.

Use of these testosterone in adolescents with gender dysphoria, is used if specific criteria listed below are met, but these medications do not have the FDA indication to be used in this population, in other words, it is "off label use".

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

The other option available is psychological therapy with a mental health provider that has experience in treating youth with gender dysphoria. We recommend this regardless of whether your child undergoes suppression of puberty or not, due to the high risk of anxiety, depression, self-harm and even suicide.

**How is testosterone taken?**

It is usually injected every one to four weeks. It is not used as a pill because the body may not absorb it properly and may cause potentially fatal liver problems. Some people use skin creams and patches, but they tend to be more expensive and aren't recommended for initiating puberty or for use in teenagers and young adults.

The doses used for injection differ from product to product and from patient to patient. They may range from 50 to 400mg. The injections are given in the muscle (intramuscular). It can also be given with a smaller needle under the skin (subcutaneous), this method is also effective in practice although it is considered “off label”. Your child may experience unwanted swings in hormone levels. They swings might be affected by how often the dose is given and how much of a dose is given.

Every medication has risks, benefits, and side effects that are important to understand before starting. The effects and side effects of medicines used for transition need to be monitored with laboratory studies and regular visits to your child’s provider to make sure that there are no negative medical or mental health effects.

Both testosterone, as well as the process of transitioning can affect your child’s mood. It is important that your child is under the care of a gender-qualified therapist while undergoing transition. The therapist can work with your child, your family and friends and your school staff.

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

In order to receive hormone replacement therapy (HRT) in our program, there are specific requirements that need to be met before and during the treatment. Although this therapy is considered standard of care, this is a new area of medicine for adolescents, and we want to provide the safest treatment possible. These requirements will allow us to monitor your child’s medical as well as mental health wellbeing during HRT. If these requirements are not met, HRT may be discontinued in the best interest and safety of your child.

Before beginning or continuing HRT your child needs to undergo a thorough psychological and social evaluation performed by licensed psychiatrist or psychologist. We also require your child has participated in at least 6 months of psychological therapy. We will need a letter from your child’s therapist confirming this as well as a letter from the a licensed psychiatrist or psychologist.

After all this has taken place, HRT can be continued if your child meets the criteria, which includes ALL of the following:

1. Fulfill the current DSM or ICD criteria for gender dysphoria or transsexualism.
2. Have pubertal changes that have resulted in an increase in gender dysphoria.
3. Do not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment.
4. Have adequate psychological and social support during treatment.
5. Have experienced puberty to at least Tanner stage 2 (first stage of puberty)

6. Demonstrate knowledge and understanding of the expected outcomes of HRT and sex reassignment surgery, as well as the medical and social risks and benefits of sex reassignment.

AND EITHER:

7. Your child is  $\geq 16$  years old and has experienced a full social transition to the desired gender for  $\geq 2$  year.

OR

8. Your child is 14-15 years of age, has experienced a full social transition to the desired gender for  $\geq 4$  years and has been on a puberty blocker for  $\geq 1$  year.

After HRT has been started, the following will be required:

1. Visits with the endocrinologist in our program every 3 months.
2. Suicide risk assessment performed by our social worker during each clinic visit every 3 months.
2. Laboratory testing every 3-6 months.
3. X ray of the hand (bone age) once a year if your child is still growing.
4. Bone (DXA) scan once a year: this will allow us to monitor your child's bone density (bone strength) during treatment, which can be altered by HRT.
5. Yearly mental health assessments by a licensed psychiatrist or psychologist. This will allow us to monitor your child's psychological wellbeing and adjustment while on HRT.
6. Continued counseling with a therapist during the treatment period, with the frequency recommended by the therapist.

### **Effects of testosterone**

#### **Who should not take testosterone?**

It should *not* be used by anyone who is pregnant or 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

Periodic blood tests to check on the effects of the hormone will be needed. Routine breast exams and pelvic exams with Pap tests should be continued, when applicable.

**Summary of Testosterone Benefits and Risks**

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



**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**

\_\_\_\_\_ I know that testosterone may be prescribed to make my adolescent appear less like a female and more like a male.

\_\_\_\_\_ I know it can take several months or longer for the effects to become noticeable. I know that no one can predict how fast – or how much – change will happen. I know that the changes may not be complete for two to five years after started.

\_\_\_\_\_ I know that the following changes 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 — possibility of being completely bald
- More, thicker, and coarser hairs on abdomen, arms, back, chest, and legs

\_\_\_\_\_ I know that the following changes could be permanent. They could 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

\_\_\_\_\_ I know that this treatment will not change my genetic sex (chromosomes).

\_\_\_\_\_ I know that testosterone may reduce my child’s ability to become pregnant, but it does not completely eliminate the risk of pregnancy. Transgender men can become pregnant while on testosterone. I agree to inform my child’s physician if my child becomes pregnant.

\_\_\_\_\_ I know that some aspects of the body will not be changed:

- Losing some fat may me breasts appear slightly smaller (if present), but that will not shrink

very much.

- The voice will deepen, but other aspects of the way your adolescent speaks may not sound more masculine.

\_\_\_\_\_ I know that there can be mood changes with these medicines. I agree to have my adolescent continue therapy with a qualified therapist.

\_\_\_\_\_ I know that using these medicines to feminize is an off-label use. This means it is not approved by the Food and Drug Administration (FDA). I know that the medicine and dose that is recommended is based on the judgment and experience of my adolescent's health care provider and there is no data in the medical literature or controlled research studies that supports the timing, dosing and type of administration of HRT.

### **Risks of Testosterone**

\_\_\_\_\_ I know the medical effects and the safety of testosterone are not completely known. There may be long-term risks that are not yet known.

\_\_\_\_\_ I know these medicines cause changes that other people will notice. Some transgender people have experienced discrimination. I know my child's clinician can help me find support resources.

\_\_\_\_\_ I realize that this treatment will not prevent serious psychiatric events such as a suicidal attempt.

\_\_\_\_\_ I know that my child should not take more testosterone than prescribed. Taking too much:

- Will increase health risks
- Won't make changes happen more quickly or more significantly
- Can cause the body to convert extra testosterone into estrogen, and that can slow down or stop my appearing more masculine.

\_\_\_\_\_ I know that 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
- More deposits of fat around the internal organs

\_\_\_\_\_ I know testosterone can damage the liver and possibly lead to liver disease and my child should be checked for possible liver damage while taking testosterone.

\_\_\_\_\_ I know testosterone can increase red blood cells and hemoglobin. This increase is usually only to what is normal for a biological man. However, there is a possibility that higher level of red blood cells and hemoglobin may increase my risk of life-threatening problems such as stroke or heart attack.

\_\_\_\_\_ I know that taking testosterone can increase the risk for diabetes (high blood sugars). It may decrease the body's response to insulin, cause weight gain, and increase deposits of fat around internal organs. This increases the risk of heart disease and stroke.

\_\_\_\_\_ I understand that continued treatment with testosterone can cause difficulties for your child's ovaries to release eggs or my child may become infertile and not be able to become pregnant.

\_\_\_\_\_ I understand that testosterone increases the risk of cancer to the uterus, ovaries, or breasts. It is unclear if testosterone therapy plays any role in HPV infection or cervical cancer.

\_\_\_\_\_ I know that testosterone causes or worsen migraines.

\_\_\_\_\_ I know that testosterone can cause emotional changes. For example, my child could become more irritable, frustrated, more aggressive or angry.

### **Requirements of Treatment with HRT**

\_\_\_\_\_ I understand and agree with all the requirements explained above, in order to receive HRT.

\_\_\_\_\_ I know that the mental health team and/or treating physician may recommend to stop treatment because it no longer outweighs the risks, there is insufficient social or psychological support, or our program requirements to treat are not met.

\_\_\_\_\_ I know 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 know that I or my child can change our mind and decide to stop treatment at any time.

\_\_\_\_\_ I agree to tell my physician if I think my child has any problems or is

unhappy with the treatment.

\_\_\_\_\_ I know that after my child turns 18, medical care will have to be transitioned to an adult endocrinologist or physician.

### **Prevention of Complications while under Treatment of HRT**

\_\_\_\_\_ 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 themselves or attempt suicide.**

\_\_\_\_\_ I know my child needs periodic medical evaluations clinic to make sure that my child is responding appropriately. This includes clinic visits with the pediatric endocrinologist or adolescent medicine 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.

\_\_\_\_\_ I understand that my physician will be required to monitor for side effects and that my child may have to be referred to another specialist if complications. I agree to take my child to those specialists as recommended.

\_\_\_\_\_ I understand that my physician will be required to continue to provide care in the event I may not have the ability to pay for visits.

\_\_\_\_\_ I understand if my child no longer meets criteria for treatment, has significant side effects that the physician or specialist feel that treatment must stopped, or my child wishes to discontinue treatment, the physician will continue to provide care through the detransition.

**PARENTAL CONSENT:**

**Our signatures below confirm that:**

- My clinician has talked with me about:
  - The benefits and risks of taking testosterone
  - The possible or likely consequences of hormone therapy
  - 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 of risks.
  - I have had enough opportunity to discuss treatment options with our child’s clinician.
  - My child is in agreement with this treatment and the signature of my child on the assent form attests to this agreement.
  - All of my questions have been answered to my satisfaction.
  - I believe I know enough to give informed consent to take, refuse, or postpone testosterone therapy for my child.

**Based on all this information:**

\_\_\_\_\_ I want my adolescent to begin or continue taking testosterone.

\_\_\_\_\_ I do not wish my adolescent to begin or continue taking testosterone at this time.

\_\_\_\_\_  
Parent or legal guardian’s name

\_\_\_\_\_  
Parent or legal guardian’s signature

\_\_\_\_\_  
Parent or legal guardian’s name

\_\_\_\_\_  
Parent or legal guardian’s signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date

\_\_\_\_\_  
Prescribing clinician's name

\_\_\_\_\_  
Prescribing clinician's signature

\_\_\_\_\_  
Date

**ASSENT OF A MINOR:**

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

\_\_\_\_\_  
Minor's name (printed)

\_\_\_\_\_  
Minor's signature

\_\_\_\_\_  
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 Name (Print)

\_\_\_\_\_  
Interpreter's signature

\_\_\_\_\_  
Date















## **Puberty Suppression Treatment for Patients with Gender Dysphoria**

### **Patient Information and Informed Parental Consent and Assent for Minors**

Before continuing treatment to your child to suppress puberty (put puberty "on hold" with "puberty blockers"), you need to be aware of the possible risks.

After your questions or concerns are addressed and you have decided to continue with puberty suppression for your child, a parent/legal guardian and your child will need to initial the statements of this form as well as sign the consent form. Both the parent/legal guardian and your child will need to sign in person. If there is more than one parent/legal guardian, both will have to sign. The second parent or guardian can give verbal content via video (by presenting photo ID) or by notarized document. Your child will also need to assent this form.

### **What are my other options if I do not wish to have my child to continue treatment for suppression of puberty?**

The other option available is psychological therapy with a mental health provider that has experience in treating youth with gender dysphoria. We recommend this regardless of whether your child undergoes suppression of puberty or not, due to the high risk of anxiety, depression, self-harm and even suicide.

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

The main mechanism by which physical changes of puberty can be put on hold is by blocking the signal from the brain to the organs that make the hormones of puberty. These hormones are estrogen and testosterone. Estrogen is made by the ovaries. Testosterone is made by the testicles.

The medications are also called "pubertal blockers" and are effective for both males and females. They should have been started only after the early physical changes of puberty. None of the medications have been approved by the Food and Drug Administration (FDA) to be used in adolescents with gender dysphoria, in other words, this is an "off label" use. This pediatric endocrinologists (children's doctors who specialize in hormones and puberty), use these medications frequently to suppress puberty in children with precocious (early) puberty which is the FDA approved indication.

Lupron and Histrelin are called GnRH analogs and are the most effective forms of treatment. Lupron is given as a monthly or every 3 month intramuscular injection and is approved for children with precocious (early) puberty. Histrelin is an implant that is placed under the skin surgically, and needs to be replaced yearly to every 2 years. Histrelin is approved

for children with precocious puberty with the brand name of Supprelin.

Provera is a pill that needs to be taken twice a day and is approved to be used in female adolescents with abnormal uterine bleeding. Provera was used for early puberty before Lupron and Histrelin were available, and is less effective in suppressing puberty. The Depo Provera injection has been approved for the use for female with abnormal bleeding as well as birth control.

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

In order to receive therapy to put puberty on “hold”, there are specific requirements that should have met before and during the treatment. These requirements will allow your physician to monitor your child’s medical as well as mental health wellbeing during hormone therapy. If these requirements were not met or are still not met, treatment with puberty blockers may be discontinued in the best interest and safety of your child.

Specific criteria include ALL of the following:

1. Fulfill the current DSM or ICD criteria for gender dysphoria or transsexualism.
2. Have pubertal changes that have resulted in an increase in gender dysphoria.
3. Do not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment.
4. Have adequate psychological and social support during treatment.
5. Have experienced puberty to at least Tanner stage 2 : this is the first stage of puberty and refers to breast or testicle growth; has to be confirmed by a physician.
6. Demonstrate knowledge and understanding of the expected outcomes of suppression of puberty, future cross-sex hormone treatment, as well as the medical and social risks and benefits of sex reassignment.

After treatment for suppression of puberty has been initiated, the following will be required:

1. Visits with the endocrinologist or adolescent medicine physician in our program every 3 months.
2. Suicide risk assessment performed by our social worker during each clinic visit every 3 months.
3. Laboratory testing every 3-4 months.
4. Xray of the hand (bone age) once a year.
5. Bone (DXA) scan: this will allow us to monitor your child’s bone density (bone strength) during treatment, since puberty blockers may decrease bone density if given for long periods of time.
6. Yearly mental health assessment by a licensed psychiatrist or psychologist. This will

allow us to monitor your child's psychological wellbeing and adjustment while on puberty blockers.

7. Continued counseling with a therapist during the treatment period, with the frequency recommended by the therapist.

**Please initial each statement on this form** to show that you understand the benefits, risks, and changes that may occur from giving treatment for suppression of puberty to your child.

**Effects of Treatment of Suppression of Puberty**

\_\_\_\_\_ I know that puberty blockers are used to temporarily suspend or block the physical changes of puberty for my child.

\_\_\_\_\_ I know that the effect of this medication should not permanent. If my child stops treatment, in a few months my child's body will restart the changes of puberty at the developmental stage they were at when they started the treatment.

\_\_\_\_\_ I know that it can take several months for the medication to be effective. I know that no one can predict how quickly or slowly or even if my child's body will respond.

\_\_\_\_\_ I know that by taking these medications, my child's body will not be making the hormones of puberty, testosterone or estrogen.

\_\_\_\_\_ I understand by using a puberty blocker, it will not will not make my child's body appear to be more male-like or female-like.

\_\_\_\_\_ I know that this treatment will not change my genetic sex (chromosomes), and it will not change my internal reproductive structures (ovaries, uterus, and vagina).

\_\_\_\_\_ I understand that puberty blockers can interferes with fertility, but it does not affect the ability to get a sexually transmitted infection. Precautions against getting an STI must still be taken.

\_\_\_\_\_ I know that the use of these medications in adolescents with gender dysphoria are off- label use. I know this means it they are not approved by the FDA for this specific diagnosis.

**Risks of Treatment of Suppression of Puberty**

\_\_\_\_\_ I know that information on adverse effects and safety of these medications used in transgender youth is not well known.

\_\_\_\_\_ I realize that this treatment will not prevent serious psychiatric events such as a suicidal attempt.

\_\_\_\_\_ I understand that some people taking pubertal blockers have had new or worsened mental (psychiatric) problems. Mental (psychiatric) problems may include emotional symptoms such as:

- Crying
- Irritability
- Restlessness (impatience)
- Anger
- Acting aggressive

\_\_\_\_\_ I agree to call my child's doctor right away if your child has any new or worsening mental symptoms or problems while taking this medication.

\_\_\_\_\_ I understand that during the first 2 to 4 weeks of treatment, puberty blockers can cause an increase in some hormones. During this time, you may notice more signs of puberty in your child, including vaginal bleeding.

\_\_\_\_\_ I understand that some people taking puberty blockers have had seizures. The risk of seizures may be higher in people who:

- Have a history of seizures
- Have a history of epilepsy
- Have a history of brain or brain vessel (cerebrovascular) problems or tumors
- Are taking a medicine that has been connected to seizures, such as bupropion or selective serotonin reuptake inhibitors (SSRIs)

Seizures have also happened in people who have not had any of these problems.

\_\_\_\_\_ I agree to call my child's doctor right away if your child has a seizure while on these medications.

\_\_\_\_\_ I understand increased pressure in the fluid around the brain can happen in children taking puberty blockers. I agree to call my child's doctor right away if your child has any of the following symptoms during treatment:

- Headache
- Eye problems including blurred vision, double vision, and decreased eyesight
- Eye pain
- Ringing in the ears
- Dizziness
- Nausea

\_\_\_\_\_ I understand that a puberty blocker should not be used taken if my child is:

- Allergic to GnRH, GnRH agonist medicines, or Progesterones.
- Pregnant or becomes pregnant. These medications can cause birth defects or loss of the baby. If your child becomes pregnant, I will notify my child's doctor.



\_\_\_\_\_ I understand the most common side effects of puberty blockers include:

- Injection site reactions such as pain, swelling, and abscess- which may result in surgery
- Weight gain
- Pain throughout body
- Headache
- Acne or red, itchy rash and white scales (seborrhea)
- Serious skin rash (erythema multiforme)
- Mood changes
- Swelling of vagina (vaginitis), vaginal bleeding, and vaginal discharge
- Upper stomach pain
- Diarrhea
- Bleeding
- Nausea and vomiting
- Fever
- Itching
- Pain in extremities
- Rash
- Back pain
- Ligament sprain
- Weight gain
- Fracture
- Breast tenderness
- Difficulty sleeping
- Chest pain
- Excessive sweating

\_\_\_\_\_ I know that the treatments to suppress puberty may decrease bone density.

\_\_\_\_\_ I know that my child may grow less than his/her peers while on these medications.

\_\_\_\_\_ I realize there may be a stalling of typical adolescent cognitive or brain development while on these medications.

\_\_\_\_\_ I know that stopping the development of puberty for my child may have social consequences.

### **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 know that the mental health team and/or treating physician may recommend to stop treatment because it no longer outweighs the risks, there is insufficient social or psychological support, or our program requirements to treat are not met. In this case, we will not continue to prescribe drug therapy.

\_\_\_\_\_ I know 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 know that I can change my mind and decide to stop treatment at any time.

\_\_\_\_\_ I agree to tell a member of our GENECIS team if you think your adolescent has any problems or is unhappy with the treatment.

\_\_\_\_\_ I know that after my child turns 21, medical care will have to 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 you have concerns that your child has worsening signs of depression or anxiety, or wants to harm him/herself or attempt suicide.

\_\_\_\_\_ I know my child needs periodic medical evaluations clinic to make sure that my child is responding appropriately. This includes clinic visits with the pediatric endocrinologist or adolescent medicine 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.

\_\_\_\_\_ I understand that my physician will be required to monitor for side effects and that my child may have to be referred to another specialist if complications.

\_\_\_\_\_ I understand that my physician will be required to continue to provide care in the event I may not have the ability to pay for visits.

\_\_\_\_\_ I understand if my child no longer meets criteria for treatment, has significant side effects that the physician or specialist feel that treatment must stopped, or my child wishes to discontinue treatment, the physician will continue to provide care through the detransition.

**PARENTAL CONSENT:**

**Our signatures below confirm that**

- My child’s health care provider has talked with me about:
  - a) the benefits and risks of puberty blockers for my child.
  - b) the possible or likely consequences of using puberty blockers.
  - c) 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 to receive puberty blockers in this program.
- I have had enough opportunity to discuss treatment options with my child’s health care provider.
- All of my questions have been answered to my satisfaction.
- 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 as prescribed.

\_\_\_\_\_ I do not wish my child to receive puberty suppression treatment at this time.

\_\_\_\_\_  
Parent or legal guardian’s name

\_\_\_\_\_  
Parent or legal guardian’s signature

\_\_\_\_\_  
Parent or legal guardian’s name

\_\_\_\_\_  
Parent or legal guardian’s signature Date

\_\_\_\_\_  
Prescribing clinician’s name

\_\_\_\_\_  
Prescribing

clinician's signature

Date

**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















## **Feminizing Medications for Patients with Gender Dysphoria**

### **Patient Information and Informed Consent and Assent for Minors**

Before starting or continuing medications to transition your affirmed gender, you need to be aware of the effects and possible risks of these medications.

Your doctor 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 affirmation process. Your doctor will discuss with you all of the information relating to starting hormone therapy. You are asked to read and understand the following information, and raise any questions you have with your doctor.

After your questions or concerns are addressed and you have decided to start or continue medications you will need to initial the statements of this form as well as sign the consent form in person with your physician.

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

Part of transition for many transgender people involves taking hormones, this is also called hormone replacement therapy or HRT. HRT in transgender girls and women means taking estrogens (female hormones), as well as medicines to block their body from producing or utilizing testosterone (male hormones). Use of these medications in adolescents with gender dysphoria, is considered if specific criteria listed below is met, but these medications do not have the FDA indication to be used in this population, in other words, it is "off label use".

Different forms of the hormone estrogen are used to feminize appearance in transgender females. Estrogen can be given as an injection to be given weekly or every other week, as a pill to be taken daily or twice a day, or as a patch to be changed weekly or every three or four days.

Medications that block the production or effects of testosterone are called androgen blockers. Androgen is another term for male sex hormones. **Spironolactone** is the androgen blocker that is most commonly used in the United States. Other medicines are sometimes used, but because spironolactone is relatively safe, inexpensive, and effective to block testosterone, it is the primary androgen blocker used for transgender girls. In some cases, **Bicalutamide** is a cancer treatment drug has been used. It is approved for the treatment for prostate cancer. Bicalutamide blocks the effects of testosterone, but does not reduce testosterone levels. Fulminant hepatotoxicity resulting in death has been described with bicalutamide. Given that bicalutamide has not been adequately studied in trans feminine populations, WPATH does not recommend its routine use. In many countries, **cyproterone acetate**, a synthetic progestogen with strong anti-androgen activity is commonly used. When paired with estrogens for transgender women, the progestin cyproterone acetate is associated with elevated prolactin, decreased HDL cholesterol, and rare meningiomas. Cyproterone has been associated with uncommon episodes of fulminant

hepatitis. The administration of **finasteride** (5 $\alpha$ -reductase inhibitor) blocks the conversion of testosterone to the more potent androgen dihydrotestosterone. The Food & Drug Administration (FDA) approved indications of administration include benign prostatic hypertrophy and androgenetic alopecia. WPATH also does not recommend their routine use in trans feminine populations. Various forms of **progestins** have also been 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 starting or continuing treatment. The effects and side effects of medicines used for transition need to be monitored with laboratory studies and regular visits to your physician to make sure that there are no negative medical and mental health effects.

All these medicines, as well as the process of transitioning can affect your mood. It is important that are under the care of a gender-qualified therapist while undergoing transition.

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

The other option available is psychological therapy with a mental health provider that has experience in treating people with gender dysphoria. We recommend this regardless of whether you undergoes suppression of puberty or not, due to the high risk of anxiety, depression, self-harm and even suicide.

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

In order to receive hormone replacement therapy (HRT), there are specific requirements that need to be met before and during the treatment. These requirements will allow us to monitor your medical as well as mental health wellbeing during HRT. If these requirements are not met, HRT may be discontinued in the best interest and safety.

Before beginning or continuing HRT you need undergo a thorough psychological and social evaluation performed by a licensed psychiatrist or psychologist. We are also required to have participated in at least 6 months of psychological therapy. We will need a letter from your therapist confirming this as well as a letter from the a licensed psychiatrist or psychologist.

After all this has taken place, HRT can be initiated or continued if ALL of the following criteria is met:

1. Fulfill the current DSM or ICD criteria for gender dysphoria or transsexualism dysphoria (a condition of feeling one's emotional and psychological identity as male or female to be opposite to one's biological sex) diagnosed by licensed psychiatrist or psychologist and that has been persistent and well documented.
2. Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed
3. Gender incongruence is marked and sustained
4. Demonstrates capacity to consent for the specific gender-affirming hormone treatment
5. Do not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment.
6. Have adequate psychological and social support during treatment.
7. Demonstrate knowledge and understanding of the expected outcomes of HRT, as well as the medical and social risks and benefits of sex reassignment.
8. Understands the effect of gender-affirming hormone treatment on reproduction and they have explored reproductive options

After HRT has been initiated, the following will be required:

1. Visits with the physician every 3 months for the first year, then every 6 months.
2. Suicide risk assessment performed during each clinic visit.
3. Laboratory testing every 3-6 months.
4. Bone mineral density scan (DXA) once a year: this will allow us to monitor your bone density (bone strength) during treatment, which can be altered by HRT.
5. Yearly mental health assessments by a licensed psychiatrist or psychologist. This will allow us to monitor your psychological wellbeing and adjustment while on HRT.
6. Continued counseling with a therapist during the treatment period, with the frequency recommended by the therapist.

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

### **Effects of Feminizing Medications**

\_\_\_\_\_ I know that estrogen, anti-androgens, or both may be prescribed to feminize my adolescent's appearance.

\_\_\_\_\_ I know it can take several months or longer for the effects to become noticeable. I know that no one can predict how fast – or how much – change will happen.

\_\_\_\_\_ I know that taking estrogen will cause the following changes in my breasts:

- I will develop breasts.
- It takes several years for breasts to get to their full size.
- The breasts will remain, even if estrogen is stopped.
- A milky discharge from the nipples may appear. If this happens, this should be checked by my physician. It could be caused by the estrogen or by something else.
- The risk of breast cancer can be increased to as high as if your adolescent had been born female.

\_\_\_\_\_ I know that the following changes may or may not occur if the medicines are stopped:

- If body hair is present, it will become less noticeable and will grow more slowly although it won't stop completely, even after taking medicines for years.
- There might be less fat on the abdomen and more on the buttocks, hips, and thighs. The fat will be redistributed to a more female shape — changing from —apple shape to —pear shape.
- You will lose muscle and strength in the upper body.
- The skin may become softer.

\_\_\_\_\_ I know that my body will make less testosterone. This may affect my sex life in different ways and the future ability for me to cause a pregnancy or have biological children:

- The testicles will shrink.
- There will be fewer spontaneous erections.
- Sperm may no longer get to mature. This could make you less likely to cause a pregnancy while taking hormones and may be a permanent change even hormone therapy is discontinued.
- There is a risk you may never produce mature sperm again and this risk is further increased if you took puberty suppressing hormones (“puberty blockers”), prior to starting feminizing medications. However, it is also possible that the sperm could still mature even while taking hormones.
- The options for sperm banking have been explained.

\_\_\_\_\_ I know that some parts of the body will not change much by using these medicines.

- If present, the hair of the beard and moustache may grow more slowly than before. It may become less noticeable, but it will not go away.

- If you went through a “male puberty” and has a “male voice”, the pitch of the voice will not rise, and the speech patterns will not become more like a woman’s. If present, the “Adam’s apple” will not shrink.

\_\_\_\_\_ **I know that there can be mood changes with these medicines. I agree to continue therapy with a qualified therapist.**

\_\_\_\_\_ I know that using these medicines to feminize is an off-label use. This means it is not approved by the Food and Drug Administration (FDA). I know that the medicine and dose that is recommended is based on the judgment and experience of my physician and there is no data in the medical literature or controlled research studies that supports the timing, dosing and type of administration of HRT.

### **Risks of Feminizing Medications**

Estrogen should not be used by anyone who has a history of

- An estrogen-dependent cancer
- A 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 followed by a specialist)

Estrogen should be used with caution and only after a full discussion of risks by anyone with:

- strong family history of breast cancer or other cancers that grow quicker when estrogens are present
- diabetes
- heart disease
- chronic hepatitis or other liver disease
- high cholesterol
- migraines or seizures
- obesity
- cigarettes/nicotine use

\_\_\_\_\_ I know that the side effects and safety of these medicines are not completely known. There may be long-term risks that are not yet known.

\_\_\_\_\_ **I realize that this treatment will not prevent serious psychiatric events such as a suicidal attempt.**

\_\_\_\_\_ I know that I should not take more medicine than prescribed. Taking too much medication:

- Will increase health risks
- Won't make changes happen more quickly or more significantly.

\_\_\_\_\_ I know these medicines can damage the liver and may lead to liver disease. Therefore, I should be checked for possible liver damage as long as my child takes them.

\_\_\_\_\_ I know these medicines cause changes that other people will notice. Some transgender

people hie experienced discrimination. I know my physician can help me find support resources.

### **Risks of Estrogen**

\_\_\_\_\_ I know that taking estrogen increases the risk of blood clots or 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 damage or death.
- Pulmonary embolism - blood clot to the lungs- which may cause permanent lung damage or death
- Stroke, which may cause permanent brain damage or death.

\_\_\_\_\_ I know that the risk of blood clots is much worse if I smoke cigarettes. The danger is so high that I should stop smoking completely if estrogen is started.

\_\_\_\_\_ I know taking estrogen can increase the deposits of fat around internal organs. This can increase the risk for diabetes (blood sugar problems) and heart disease. Both of these disorders further increase the risk of heart attack and stroke.

\_\_\_\_\_ I know taking estrogen can raise blood pressure which also further increase the risk of heart attack and stroke.

\_\_\_\_\_ I know that taking estrogen increases the risk of gallstones (stones in the gallbladder), and I will talk to my physician if severe or long-lasting pain in the abdomen occurs.

\_\_\_\_\_ I know that estrogen can cause nausea and vomiting, and I should talk with my physician if long-lasting nausea or vomiting occurs.

\_\_\_\_\_ I know that estrogen can cause migraines or make them worse if I already have them.

\_\_\_\_\_ I know that estrogen can cause hot flashes

\_\_\_\_\_ I know that estrogen can cause me to feel tired or have difficulty in focusing.

\_\_\_\_\_ I know taking estrogen increases the risk of elevated prolactin level and/or a prolactinomas. These are non-cancerous tumors of the pituitary gland. I know they are not usually life threatening, but they can damage vision and cause headaches if they are not treated properly. Therefore, if I have changes in vision, headaches that are worse when waking up in the morning, and/or a milky discharge from the nipples, these can be signs of a prolactinoma, and I will talk to my physician. There is a blood test that can check for this.



### **Risks of Androgen Antagonists**

\_\_\_\_\_ I know that spironolactone affects the balance of water and salt balance in the kidneys. This may:

- Increase the amount of urine produced, making it necessary to urinate more frequently.
- Increase thirst.
- Increase risk of dehydration (not having enough water), and you should make sure to drink plenty of water. If you are peeing less than usual or have dark, strong smelling pee, feel thirsty or feel dizzy or light-headed – these can be signs of dehydration.

\_\_\_\_\_ I know that spironolactone affects the balance of potassium balance in the kidneys. This may cause high levels of potassium which:

- Can cause changes in heart rhythms that may be life threatening.
- Reduce blood pressure or cause low blood pressure which can cause fatigue, lightheadedness
- tingling feeling
- muscle weakness
- shortness of breath

\_\_\_\_\_ I understand that my doctor will perform a blood test to monitor this risk while on the medication.

### **Requirements of Treatment with HRT**

\_\_\_\_\_ I understand and agree with all the requirements explained above, in order to receive HRT.

\_\_\_\_\_ I know that the mental health team and/or treating physician may recommend to stop treatment because it no longer outweighs the risks, there is insufficient social or psychological support, or our program requirements to treat are not met.

\_\_\_\_\_ I know 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 know that I can change our mind and decide to stop treatment at any time.

### **Prevention of Complications while under Treatment of HRT**

\_\_\_\_\_ I agree to tell my health care provider if I have any problems or side effects or am unhappy with the medications, and in particular, **if I have concerns that I have worsening signs of depression or anxiety, or wants to harm myself or attempt suicide.**

\_\_\_\_\_ I know I need periodic medical evaluations clinic to make sure that I am responding appropriately. This includes clinic visits with my physician every 3 months in the first year and every 6 months thereafter as well as laboratory and imaging tests.

\_\_\_\_\_ I acknowledge that gender affirming hormones are only a part of my overall health, and that a range of preventative health activities are recommended so that I remain happy and healthy in my affirmed gender. These include but are not limited to:

- Monthly breast self-examination. I should tell my doctor if I discover any new lumps
- Regular breast mammograms from an appropriate age, in consultation with my doctor
- Prostate examination per guidelines
- 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

\_\_\_\_\_ I agree to continue with psychological therapy or counseling with the frequency recommended by my therapist.

\_\_\_\_\_ I understand that my physician will be required to monitor for side effects and that my may have to be referred to another specialist if complications. I agree to go to the specialists as recommended.

\_\_\_\_\_ I understand that my physician will be required to continue to provide care in the event I may not have the ability to pay for visits.

\_\_\_\_\_ I understand if I no longer meet criteria for treatment, have significant side effects, my physician or specialist feel that treatment must stopped, or I wish to discontinue treatment, my physician will continue to provide care through the detransition

**My signature below confirms that:**

- My clinician has talked with me about:
  - The benefits and risks of taking feminizing medication
  - The possible or likely consequences of hormone therapy
  - 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 of risks.
- I have had enough opportunity to discuss treatment options with my physician.
- All of my questions have been answered to my satisfaction.
- I believe I know enough to give informed consent to take, refuse, or postpone therapy for myself with feminizing medications.

**Based on all this information:**

\_\_\_\_\_ I want to begin or continue taking estrogen.

\_\_\_\_\_ I want to begin or continue taking androgen antagonists.

\_\_\_\_\_ I do not wish to begin or continue taking feminizing medication at this time.

\_\_\_\_\_  
Legal name

\_\_\_\_\_  
Legal signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Prescribing clinician's name

\_\_\_\_\_  
Prescribing clinician's signature

\_\_\_\_\_  
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 Name (Print)

\_\_\_\_\_  
Interpreter's signature

\_\_\_\_\_  
Date

















## **Testosterone Treatment for Patients with Gender Dysphoria**

### **Patient Information and Informed Consent**

Before starting or continuing medications to transition your affirmed gender, you need to be aware of the effects and possible risks of these medications.

Your doctor 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 affirmation process. Your doctor will discuss with you all of the information relating to starting hormone therapy. You are asked to read and understand the following information, and raise any questions you have with your doctor.

After your questions or concerns are addressed and you have decided to start or continue medications you will need to initial the statements of this form as well as sign the consent form in person with your physician.

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

Part of transition for many transgender people involves taking hormones, this is also called hormone replacement therapy or HRT. HRT in transgender males means taking **testosterone**. This is the sex hormone that makes certain features appear typically male. It builds muscle and causes the development of facial hair and a deeper voice. It is usually injected every one to four weeks. It is not used as a pill because the body may not absorb it properly and may cause potentially fatal liver problems. Some people use skin creams and patches.

The doses used for injection differ from product to product and from patient to patient. They may range from 50 to 400 mg. Injections are given in the muscle (intramuscular). It can also be given with a smaller needle under the skin (subcutaneous), this method of practice although it is considered "off label". You may experience unwanted swings in hormone levels. The swings might be affected by how often the dose is given and how much of a dose is given.

**Finasteride** may be an appropriate treatment option in trans masculine individuals experiencing bothersome alopecia resulting from higher dihydrotestosterone levels. The administration of 5 $\alpha$ -reductase inhibitors block the conversion of testosterone to the more potent androgen dihydrotestosterone. The Food & Drug Administration (FDA) approved indications of finasteride administration include benign prostatic hypertrophy and androgenetic alopecia. The use of 5 $\alpha$ -reductase inhibitors in trans feminine populations is very sparse but treatment with a may impair clitoral growth and the development of facial and body hair in trans masculine individuals. Studies are needed to assess the efficacy and safety of 5 $\alpha$ -reductase inhibitors in transgender populations.

Use of testosterone with gender dysphoria is used if specific criteria listed below are met, but these medications do not have the FDA indication to be used in this population, in other words,

it is “off label use”.

Every medication has risks, benefits, and side effects that are important to understand before starting. The effects and side effects of medicines used for transition need to be monitored with laboratory studies and regular visits to your physician to make sure that there are no negative medical or mental health effects.

Both testosterone, as well as the process of transitioning can affect your mood. It is important that you are under the care of a gender-qualified therapist while undergoing transition. The therapist can work with your child, your family and friends and your school staff.

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

The other option available is psychological therapy with a mental health provider that has experience in treating people with gender dysphoria. We recommend this regardless of whether you undergoes suppression of puberty or not, due to the high risk of anxiety, depression, self-harm and even suicide.

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

In order to receive hormone replacement therapy (HRT), there are specific requirements that need to be met before and during the treatment. These requirements will allow us to monitor your medical as well as mental health wellbeing during HRT. If these requirements are not met, HRT may be discontinued in the best interest and safety.

Before beginning or continuing HRT you need undergo a thorough psychological and social evaluation performed by a licensed psychiatrist or psychologist. We are also required to have participated in at least 6 months of psychological therapy. We will need a letter from your therapist confirming this as well as a letter from the a licensed psychiatrist or psychologist.

After all this has taken place, HRT can be initiated or continued if ALL the following criteria is met:

1. Fulfill the current DSM or ICD criteria for gender dysphoria or transsexualism dysphoria (a condition of feeling one's emotional and psychological identity as male or female to be opposite to one's biological sex) diagnosed by licensed psychiatrist or psychologist and that has been persistent and well documented.
2. Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed.
3. Gender incongruence is marked and sustained.
4. Demonstrates capacity to consent for the specific gender-affirming hormone treatment.
5. Do not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment.
6. Have adequate psychological and social support during treatment.
7. Demonstrate knowledge and understanding of the expected outcomes of HRT, as well as the medical and social risks and benefits of sex reassignment.
8. Understands the effect of gender-affirming hormone treatment on reproduction and they have explored reproductive options.

After HRT has been initiated, the following will be required:

1. Visits with the physician every 3 months for the first year, then every 6 months.
2. Suicide risk assessment performed during each clinic visit.
3. Laboratory testing every 3-6 months.
4. Bone mineral density scan (DXA) once a year: this will allow us to monitor your bone density (bone strength) during treatment, which can be altered by HRT.
5. Yearly mental health assessments by a licensed psychiatrist or psychologist. This will allow us to monitor your psychological wellbeing and adjustment while on HRT.

Continued counseling with a therapist during the treatment period, with the frequency recommended by the therapist.

### **Effects of testosterone**

#### **Who should not take testosterone?**

It should *not* be used by anyone who is pregnant or 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

Periodic blood tests to check on the effects of the hormone will be needed. Routine breast exams and pelvic exams with Pap tests should be continued, when applicable.

**Summary of Testosterone Benefits and Risks**

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

**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**

\_\_\_\_\_ I know that testosterone may be prescribed to make me appear less like a female and more like a male.

\_\_\_\_\_ I know it can take several months or longer for the effects to become noticeable. I know that no one can predict how fast – or how much – change will happen. I know that the changes may not be complete for two to five years after started.

\_\_\_\_\_ I know that the following changes 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 — possibility of being completely bald
- More, thicker, and coarser hairs on abdomen, arms, back, chest, and legs

\_\_\_\_\_ I know that the following changes could be permanent. They could 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

\_\_\_\_\_ I know that this treatment will not change my genetic sex (chromosomes).

\_\_\_\_\_ I know that testosterone may reduce my ability to become pregnant, but it does not completely eliminate the risk of pregnancy. Transgender men can become pregnant while on testosterone. I agree to inform my physician if I become pregnant.

\_\_\_\_\_ I know that some aspects of the body will not be changed:

- Losing some fat may make my breasts appear slightly smaller, but that will not shrink very much.
- The voice will deepen, but other aspects of the way I speak may not sound more masculine.



\_\_\_\_\_ **I know that there can be mood changes with these medicines. I agree to continue therapy with a qualified therapist.**

\_\_\_\_\_ I know that using these medicines to feminize is an off-label use. This means it is not approved by the Food and Drug Administration (FDA). I know that the medicine and dose that is recommended is based on the judgment and experience of my physician and there is no data in the medical literature or controlled research studies that supports the timing, dosing and type of administration of HRT.

### **Risks of Testosterone**

\_\_\_\_\_ I know the medical effects and the safety of testosterone are not completely known. There may be long-term risks that are not yet known.

\_\_\_\_\_ I know these medicines cause changes that other people will notice. Some transgender people have experienced discrimination. I know my clinician can help me find support resources.

\_\_\_\_\_ **I realize that this treatment will not prevent serious psychiatric events such as a suicidal attempt.**

\_\_\_\_\_ I know that I should not take more testosterone than prescribed. Taking too much:

- Will increase health risks.
- Won't make changes happen more quickly or more significantly.
- Can cause the body to convert extra testosterone into estrogen, and that can slow down or stop my appearing more masculine.

\_\_\_\_\_ I know that 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
- More deposits of fat around the internal organs

\_\_\_\_\_ I know testosterone can damage the liver and possibly lead to liver disease and I should be checked for possible liver damage while taking testosterone.

\_\_\_\_\_ I know testosterone can increase red blood cells and hemoglobin. This increase is usually only to what is normal for a biological man. However, there is a possibility that higher level of red blood cells and hemoglobin may increase the risk of life-threatening problems such as stroke or heart attack.

\_\_\_\_\_ I know that taking testosterone can increase the risk for diabetes (high blood sugars). It

may decrease the body's response to insulin, cause weight gain, and increase deposits of fat around internal organs. This increases the risk of heart disease and stroke.

\_\_\_\_\_ I understand that continued treatment with testosterone can cause difficulties for my ovaries to release eggs or I may become infertile and not be able to become pregnant.

\_\_\_\_\_ I understand that testosterone increases the risk of cancer to the uterus, ovaries, or breasts. It is unclear if testosterone therapy plays any role in HPV infection or cervical cancer.

\_\_\_\_\_ I know that testosterone causes or worsen migraines.

\_\_\_\_\_ I know that testosterone can cause emotional changes. For example, I could become more irritable, frustrated, more aggressive or angry.

### **Risks of Finasteride**

\_\_\_\_\_ I know that finasteride may be an appropriate treatment option in trans masculine individuals experiencing bothersome alopecia resulting from testosterone treatment.

\_\_\_\_\_ I know that finasteride may be an appropriate treatment option in trans masculine individuals experiencing bothersome alopecia resulting from testosterone treatment.

\_\_\_\_\_ I know that finasteride may side effects which include:

- decreased libido
- dry skin
- acne
- Breast swelling and tenderness
- headache
- irregular menstruation
- dizziness
- increased body hair

\_\_\_\_\_ I understand that finasteride is not approved FDA for use in transmen and is forbidden in pregnant women due to birth defects.

### **Requirements of Treatment with HRT**

\_\_\_\_\_ I understand and agree with all the requirements explained above, in order to receive HRT.

\_\_\_\_\_ I know that the mental health team and/or treating physician may recommend to stop treatment because it no longer outweighs the risks, there is insufficient social or psychological support, or our program requirements to treat are not met.

\_\_\_\_\_ I know 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 know that I can change our mind and decide to stop treatment at any time.

### **Prevention of Complications while under Treatment of HRT**

\_\_\_\_\_ I agree to tell my health care provider if I have any problems or side effects or am unhappy with the medication, and in particular, **if I have concerns that I have worsening signs of depression or anxiety, or wants to harm myself or attempt suicide.**

\_\_\_\_\_ I know I need periodic medical evaluations clinic to make sure that I am responding appropriately. This includes clinic visits with my physician every 3 months in the first year and every 6 months thereafter as well as laboratory and imaging tests.

\_\_\_\_\_ I agree to continue psychological therapy or counseling with the frequency recommended by his therapist.

\_\_\_\_\_ I understand that my physician will be required to monitor for side effects and that I have to be referred to another specialist if complications. I agree to take my child to those specialists as recommended.

\_\_\_\_\_ I acknowledge that gender affirming hormones are only a part of my overall health, and that a range of preventative health activities are recommended so that I remain happy and healthy in my affirmed gender. These include but are not limited to:

- Cervical screening tests at appropriate intervals, as recommended by my doctor
- Regularly checking my chest / breasts for lumps, even if I have had a mastectomy
- Regular breast mammograms from an appropriate age, in consultation with my doctor
- Quitting smoking
- Immunisations
- 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

\_\_\_\_\_ I understand that my physician will be required to continue to provide care in the event I may not have the ability to pay for visits.

\_\_\_\_\_ I understand if I no longer meet criteria for treatment, have significant side effects that the physician or specialist feel that treatment must stopped, or I wish to discontinue treatment, the physician will continue to provide care through the detransition.

**My signature below confirms that:**

- My clinician has talked with me about:
  - The benefits and risks of taking testosterone
  - The possible or likely consequences of hormone therapy
  - 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 of risks.
- I have had enough opportunity to discuss treatment options with my physician
- All of my questions have been answered to my satisfaction.
- I believe I know enough to give informed consent to take, refuse, or postpone testosterone therapy.

**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 at this time.

\_\_\_\_\_  
Legal name

\_\_\_\_\_  
Legal signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Prescribing clinician's name

\_\_\_\_\_  
Prescribing clinician's signature

\_\_\_\_\_  
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 Name (Print)

\_\_\_\_\_  
Interpreter's signature

\_\_\_\_\_  
Date



















