to compensate the patient. Only after those sanctions have been imposed may the disciplining authority consider and include in the order requirements designed to rehabilitate the physician. All costs associated with compliance with orders issued under this subsection are the obligation of the physician.

(3) In any administrative action against a physician which does not involve revocation or suspension of license, the division shall have the burden, by the greater weight of the evidence, to establish the existence of grounds for disciplinary action. The division shall establish grounds for revocation or suspension of license by clear and convincing evidence.

(4) The board shall not reinstate the license or certificate of an osteopathic physician, or cause a license or certificate to be issued to a person it has deemed unqualified, until such time as it is satisfied that he or she has complied with all the terms and conditions set forth in the final order and that such person is capable of safely engaging in the practice of osteopathic medicine. However, the board may not issue a license to, or reinstate the license of, any medical doctor found by the board to have committed repeated medical malpractice based on s. **456.50**, regardless of the extent to which the licensee or prospective licensee has complied with all terms and conditions set forth in the final order and is capable of safely engaging in the practice of osteopathic medicine.

(5) The board shall, by rule, establish comprehensive guidelines for the disposition of disciplinary cases involving specific types of violations. Such guidelines shall establish offenses and circumstances for which revocation will be presumed to be appropriate, as well as offenses and circumstances for which suspension for particular periods of time will be presumed to be appropriate. The guidelines shall also establish minimum and maximum fines, periods of supervision or probation, or conditions of probation and conditions for reissuance of a license with respect to particular circumstances and offenses. “Gross medical malpractice,” “repeated medical malpractice,” and “medical malpractice,” under paragraph (1)(x) shall each be considered distinct types of violations requiring specific individual guidelines.

(6) Upon the department’s receipt from an insurer or self-insurer of a report of a closed claim against an osteopathic physician pursuant to s. **627.912** or from a health care practitioner of a report pursuant to s. **456.049**, or upon the receipt from a claimant of a presuit notice against an osteopathic physician pursuant to s. **766.106**, the department shall review each report and determine whether it potentially involved conduct by a licensee that is subject to disciplinary action, in which case the provisions of s. **456.073** shall apply. However, if it is reported that an osteopathic physician has had three or more claims with indemnities exceeding $50,000 each within the previous 5-year period, the department shall investigate the occurrences upon which the claims were based and determine if action by the department against the osteopathic physician is warranted.

(7) Upon the department’s receipt from the Agency for Health Care Administration pursuant to s. **395.0197** of the name of an osteopathic physician whose conduct may constitute grounds for disciplinary action by the department, the department shall investigate the occurrences upon which the report was based and determine if action by the department against the osteopathic physician is warranted.

(8) If any osteopathic physician regulated by the Division of Medical Quality Assurance is guilty of such unprofessional conduct, negligence, or mental or physical incapacity or impairment that the division determines that the osteopathic physician is unable to practice with reasonable skill and safety and presents a danger to patients, the division shall be authorized to maintain an action in circuit court enjoining such osteopathic physician from providing medical services to the public until the osteopathic physician demonstrates the ability to practice with reasonable skill and safety and without danger to patients.

(9) When an investigation of an osteopathic physician is undertaken, the department shall promptly furnish to the osteopathic physician or his or her attorney a copy of the complaint or document which resulted in the initiation of the investigation. For purposes of this subsection, such documents include, but are not limited to: the pertinent portions of an annual report submitted to the department pursuant to s. **395.0197**(6); a report of an adverse incident which is provided to the department pursuant to s. **395.0197**; a report of peer review disciplinary action submitted to the department pursuant to s. **395.0193**(4) or s. **459.016**, provided that the investigations, proceedings, and records relating to such

766.305(2). The osteopathic physician may submit a written response to the information contained in the complaint or document which resulted in the initiation of the investigation within 45 days after service to the osteopathic physician of the complaint or document. The osteopathic physician's written response shall be considered by the probable cause panel.

(10) A probable cause panel convened to consider disciplinary action against a physician assistant alleged to have violated s. 456.072 or this section must include one physician assistant. The physician assistant must hold a valid license to practice as a physician assistant in this state and be appointed to the panel by the Council of Physician Assistants. The physician assistant may hear only cases involving disciplinary actions against a physician assistant. If the appointed physician assistant is not present at the disciplinary hearing, the panel may consider the matter and vote on the case in the absence of the physician assistant. The training requirements set forth in s. 458.307(4) do not apply to the appointed physician assistant. Rules need not be adopted to implement this subsection.

(11) The purpose of this section is to facilitate uniform discipline for those acts made punishable under this section and, to this end, a reference to this section constitutes a general reference under the doctrine of incorporation by reference.

History.—ss. 1, 6, ch. 79-230; s. 3, ch. 80-354; s. 305, ch. 81-259; ss. 2, 3, ch. 81-318; s. 19, ch. 83-329; s. 2, ch. 85-6; s. 5, ch. 85-175; ss. 16, 27, 29, ch. 86-290; s. 54, ch. 87-225; s. 35, ch. 88-1; s. 13, ch. 88-277; s. 3, ch. 90-44; s. 27, ch. 90-228; s. 3, ch. 90-254; s. 63, ch. 91-220; s. 4, ch. 91-429; s. 40, ch. 92-149; s. 2, ch. 92-178; s. 84, ch. 92-289; s. 29, ch. 95-144; s. 221, ch. 96-410; s. 1097, ch. 97-103; s. 107, ch. 97-261; s. 33, ch. 97-264; s. 38, ch. 98-89; s. 52, ch. 98-166; s. 223, ch. 99-8; s. 103, ch. 99-397; s. 111, ch. 2000-160; ss. 25, 77, ch. 2001-277; s. 27, ch. 2003-416; s. 4, ch. 2004-303; s. 4, ch. 2005-240; s. 4, ch. 2005-266; s. 2, ch. 2006-242; s. 77, ch. 2008-6; s. 10, ch. 2010-211; s. 9, ch. 2011-141; s. 5, ch. 2011-233; s. 3, ch. 2013-166; s. 18, ch. 2016-145; s. 10, ch. 2016-222; s. 22, ch. 2016-224; s. 9, ch. 2017-41; ss. 1, 5, ch. 2017-232; s. 15, ch. 2018-13; s. 53, ch. 2018-106; s. 8, ch. 2019-112; s. 7, ch. 2019-130; s. 5, ch. 2020-31; s. 15, ch. 2022-35.

[1]Note.—Section 1, ch. 2017-232, provides that "[i]t is the intent of the Legislature to implement s. 29, Article X of the State Constitution by creating a unified regulatory structure. If s. 29, Article X of the State Constitution is amended or a constitutional amendment related to cannabis or marijuana is adopted, this act shall expire 6 months after the effective date of such amendment." If such amendment or adoption takes place, paragraph (1)(ww), as created by s. 5, ch. 2017-232, is repealed.

FLORIDA BOARD OF MEDICINE AND FLORIDA BOARD OF OSTEOPATHIC MEDICINE APPROVED INFORMED CONSENT FORM FOR CATARACT OPERATION WITH OR WITHOUT IMPLANTATION OF INTRAOCULAR LENS

DOES THE PATIENT NEED OR WANT A TRANSLATOR, INTERPRETOR OR READER?
YES_____NO_____

TO THE PATIENT: You have the right, as a patient, to be informed about your cataract condition and the recommended surgical procedure to be used, so that you may make the decision whether or not to undergo the cataract surgery, after knowing the risks, possible complications, and alternatives involved. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed so that you may give or withhold your consent to cataract surgery and should reflect the information provided by your eye surgeon. If you have any questions or do not understand the information, please discuss the procedure with your eye surgeon prior to signing.

WHAT IS A CATARACT, AND HOW IS IT TREATED?

The lens in the eye can become cloudy and hard, a condition known as a cataract. Cataracts can develop from normal aging, from an eye injury, various medical conditions or if you have taken certain medications such as steroids. Cataracts may cause blurred vision, dulled vision, sensitivity to light and glare, and/or ghost images. If the cataract changes vision so much that it interferes with your daily life, the cataract may need to be removed to try to improve your vision. Surgery is the only way to remove a cataract. You can decide to postpone surgery or not to have the cataract removed.

ALTERNATIVE TREATMENTS:

I understand that I may decide not to have a cataract operation, at all. However, if I do not have the cataract surgery, I understand my vision loss from the cataract usually will continue to get worse. Corrective lenses, eyeglasses, or contact lenses will not improve my vision or reverse the worsening of the cataract.

HOW WILL REMOVING THE CATARACT AFFECT MY VISION?

The goal of cataract surgery is to correct the decreased vision that was caused by the cataract. During the surgery, the ophthalmologist (eye surgeon) removes the cataract and may place in a new artificial lens called an intraocular lens or IOL. Cataract surgery will **not** correct other causes of decreased vision, such as glaucoma, optic nerve or retinal problems, diabetes, age- related macular degeneration, or dry eye. In order to obtain the best possible vision, many people still need to wear glasses or contact lenses after cataract surgery for either near and/or distance vision, for some activities, or in low light.

WHAT ARE THE TYPES OF INTRA-OCULAR-LENSES (IOL) THAT ARE AVAILABLE FOR ME?

Your ophthalmologist will help you decide on the type of IOL that will replace your cloudy lens. There are IOLs available to treat nearsightedness (myopia), farsightedness (hyperopia), and astigmatism. IOLs usually provide either near or distance vision-- these single focus lenses are called **monofocal IOLs**. Some more recently developed IOLs may provide for near, intermediate, and distance vision-- these multiple focus lenses are called **multifocal IOLs**. Lenses that have some focusing power are called **accommodative IOLs**. IOLs that treat astigmatism are called **toric IOLs**.

You can also have one eye corrected for near vision, and the other for distance vision, a choice called **monovision**. With monovision the implanted IOLs have two different powers, one for near vision in one eye, and one for distance vision in the other eye. Monovision allows for near and distance vision but can decrease depth perception. Although many patients adjust well to monovision, some may find it uncomfortable, which may require compensating glasses, contact lenses or another operation to change the IOL.

No IOL is perfect, and often glasses or contact lenses are needed for certain activities even if you have chosen a special IOL lens.

DO I HAVE ASTIGMATISM IN ADDITION TO MY CATARACT? ARE THERE TREATMENTS FOR IT?

Patients with nearsightedness and farsightedness may also have astigmatism. Astigmatism is caused by an irregularly shaped cornea; instead of being round like a basketball, the cornea is shaped like an American style football. This can make your vision blurry. In addition to toric IOLs, astigmatism can be reduced by glasses, contact lenses, and refractive surgery (Laser assisted in situ keratomileusis [LASIK] or Photorefractive keratectomy [PRK]).

There is also a procedure called a limbal relaxing incision (LRI), which can be done at the same time as the cataract operation, or as a separate procedure. A LRI is a small cut or incision the ophthalmologist makes into your cornea to make its shape more round. Astigmatic Keratotomy (AK) is a similar procedure that involves a smaller, more central incision in the cornea than the LRI.

Any attempt at astigmatism reduction could result in over- or under-correction, in which case glasses, contact lenses, or another procedure may be needed. None of the methods of reducing astigmatism are perfect or completely predictable, but all are designed to help reduce the amount

of astigmatism present.

WHAT ARE THE RECOGNIZED RISKS OF CATARACT SURGERY?

All operations and surgical procedures have risks and can have unsuccessful results or associated complications that can injure the patient, or even cause death in some instances. The recognized, specific risks of cataract surgery include problems that can lead to loss of vision, blindness or loss of your eye. Those risks include: bleeding; infection; high eye pressure; a swollen or detached retina; a droopy eyelid; double vision; displacement of the lens or portion (fragments) of the lens; injury to the cornea, iris, sclera, conjunctivae, pupil function, or other parts of the eye and nearby structures, from the operation or the anesthesia. Sometimes pieces of the lens cannot be completely removed and the vitreous can become displaced.

The specific, recognized, risks of a Limbal Relaxing Incision (LRI) or Astigmatic Keratectomy (AK), if performed in conjunction with cataract surgery are similar to those for cataract surgery, but also include perforation to the cornea, damage to the iris, increased astigmatism, and scarring, which could cause loss of vision. Furthermore, the LRI or AK may not fully correct the astigmatism and an under- or over-correction could occur, and glasses, contacts, or another surgical procedure may be needed to correct the vision.
Depending upon your eye and the type of IOL that is used, the most serious, recognized side effects include: increased night glare or halos, double vision, ghost images, impaired depth perception, decreased contrast, blurry vision, and decreased night vision.

At the time of surgery, your ophthalmologist may decide not to implant an IOL even though you may have given prior permission to do so, or your ophthalmologist may decide to implant an IOL different from the one that you initially preferred, or agreed to on pages four and five. In addition, the IOL may later need to be repositioned, replaced, or removed by way of a subsequent surgical procedure.

No intraocular lens or power calculation is perfect and you will likely still need glasses. Calculating IOL power is difficult in patients who are highly nearsighted or farsighted, as well as in patients that have had previous eye surgeries such as cornea surgery, glaucoma surgery, refractive surgery or retina surgery. This difficulty in calculating IOL power may result in your post-operative prescription being different from what you and the doctor thought it would be. This may require you to wear glasses, contact lenses, need refractive surgery, or have an IOL exchange or piggyback lens placed. Furthermore, because only one eye is operated on at a time, you may experience a feeling of imbalance between the two eyes which may require correction.

There is no guarantee that cataract surgery or astigmatism reduction will improve your vision, even with glasses or contacts. You may need glasses or contacts for best vision. In some cases, complications may occur weeks, months or even years later.

OTHER RISKS FROM CATARACT SUGERY:

Depending upon the type of anesthesia that is used, other risks are possible. Local anesthesia may affect or damage the retina, the optic nerve and may lead to: bleeding behind the eye, double vision, and permanent vision loss, perforation of the eye, cardiopulmonary complications, and in rare cases coma or death.

If you have **OTHER KNOWN MEDICAL CONDITIONS**, such as heart disease, history of heart failure, or lung disease such as Asthma or Chronic Obstructive Pulmonary Disease, or if you are **TAKING MEDICATIONS** such as Coumadin (a blood thinner) **OR OTHER SUPPLEMENTS OR VITAMINS**, tell your ophthalmologist so that you can minimize the risk of additional complications during and after surgery.

WHAT ARE MY OUT OF POCKET COSTS?

There is usually an additional charge for multifocal, accommodating, and toric IOLs, which is not paid by insurance. Therefore you understand that you may be responsible for that additional charge.

In some cases, additional sutures to support the IOL or wound, or a vitrectomy (or other additional surgery) may be needed at the time of the procedure or at a later time. The cost for additional surgery is not included in the price paid for the cataract surgery.

I understand that I may need additional treatment with medicines or surgery after my cataract removal. One common occurrence after cataract surgery is a clouding of the capsule behind the IOL requiring a laser treatment months or years later. This additional treatment is not included in the fee for this procedure.

PATIENT'S ACCEPTANCE OF RISKS:

I have read this informed consent (or it has been read to me) and I fully understand it and the possible alternatives to cataract surgery, the risks, complications, and benefits that can result from that surgery.

By signing below, I (we) certify that this form has been fully explained to me (us), that I (we) have filled in all the blank spaces, and that my ophthalmologist has answered all of my (our) questions, and I (we) understand and accept the risks, benefits, and understand the alternatives of cataract surgery.

The surgery is on my_____RIGHT EYE _____LEFT EYE

_____I am aware of the recognized specific risks related to cataract surgery that are described in this form.

_____I am aware that no intraocular lens is perfect, and that I may still need to use glasses or contacts for at least some activities or in low light regardless of the type of lens implanted. I am aware that no intraocular lens calculation is perfect, and that it is more difficult in an eye that has had prior corneal surgery or retinal or glaucoma surgery. I am also aware that the intraocular lens may later need to be repositioned, replaced, or removed by way of a subsequent surgical procedure.

On the advice of my Ophthalmologist, he/she and I choose the following premium lenses:

_____Multifocal Intraocular Lens

_____Toric Intraocular Lens (Right eye near/distance; Left eye near/distance).

_____Accommodative Intraocular Lens

_____Monofocal/Monovision lens (Right eye near/distance; Left eye near/distance).

_____Other_____

_____I understand that if during surgery, my ophthalmologist is unable to use any of the premium lenses; I consent to the implantation of a Monofocal Intraocular Lens.

_____I am aware of the recognized specific risks related to Limbal Relaxing Incision (LRI) or Astigmatic Keratectomy (AK) for Astigmatism Reduction are those that are described in this form, and I understand that any of these risks could result in loss of vision, blindness or loss of the eye, and may require me to undergo further surgery. Furthermore, the LRI or AK may not fully correct the astigmatism, and glasses, contacts, or another surgical procedure may be needed to correct the vision.

_____On the basis of the above statements, I voluntarily consent and authorize this cataract surgery procedure.

_____I am aware that I have the right to report adverse incidents to the Florida Board of Medicine or the Florida Board of Osteopathic Medicine.

Patient Print Name: _____

Patient Signature: _____

Date:_____**Time:** _____

(Or person authorized to sign for patient)

Witness Print Name: _____

Witness Signature: _____

Date:_____**Time:** _____

Surgeon Print Name: _____

Surgeon Signature: _____

Date:_____**Time:** _____

Medical Marijuana Consent Form

A qualified physician may not delegate the responsibility of obtaining written informed consent to another person. The qualified patient, or the patient's parent or legal guardian if the patient is a minor, must initial each section of this consent form to indicate that the physician explained the information and, along with the qualified physician, must sign and date the informed consent form.

This consent form contains three parts. Part A must be completed by all patients. Part B is only required for patients under the age of 18 with a diagnosed terminal condition who receive a certification for medical marijuana in a smokable form. Part C is the signature block and must be completed by all patients.

Part A: Must be completed for all medical marijuana patients

a. The Federal Government's classification of marijuana as a Schedule I controlled substance.

_____ The federal government has classified marijuana as a Schedule I controlled substance. Schedule I substances are defined, in part, as having (I) a high potential for abuse; (2) no currently accepted medical use in treatment in the United States; and (3) a lack of accepted safety for use under medical supervision. Federal law prohibits the manufacture, distribution and possession of marijuana even in states, such as Florida, which have modified their state laws to treat marijuana as a medicine.

_____ When in the possession of medical marijuana, the patient or the patient's caregiver must have his or her medical marijuana use registry identification card in his or her possession at all times.

b. The approval and oversight status of marijuana by the Food and Drug Administration.

_____ Marijuana has not been approved by the Food and Drug Administration for marketing as a drug. Therefore, the "manufacture" of marijuana for medical use is not subject to any federal standards, quality control, or other federal oversight. Marijuana may contain unknown quantities of active ingredients, which may vary in potency, impurities, contaminants, and substances in addition to THC, which is the primary psychoactive chemical component of marijuana.

c. The potential for addiction.

_____ Some studies suggest that the use of marijuana by individuals may lead to a tolerance to, dependence on, or addiction to marijuana. I understand that if I require increasingly higher doses to achieve the same benefit or if I think that I may be developing a dependency on marijuana, I should contact Dr._____(name of qualified physician).

d. The potential effect that marijuana may have on a patient's coordination, motor skills, and cognition, including a warning against operating heavy machinery, operating a motor vehicle, or engaging in activities that require a person to be alert or respond quickly.

_____ The use of marijuana can affect coordination, motor skills and cognition, i.e., the ability to think, judge and reason. Driving under the influence of cannabis can double the risk of vehicular accident, which escalates if alcohol is also influencing the driver. While using medical marijuana, I should not drive, operate heavy machinery or engage in any activities that require me to be alert and/or respond quickly and I should not participate in activities that may be dangerous to myself or others. I

understand that if I drive while under the influence of marijuana, I can be arrested for "driving under the influence."

e. The potential side effects of medical marijuana use.

_____ Potential side effects from the use of marijuana include, but are not limited to, the following: dizziness, anxiety, confusion, sedation, low blood pressure, impairment of short term memory, euphoria, difficulty in completing complex tasks, suppression of the body's immune system, may affect the production of sex hormones that lead to adverse effects, inability to concentrate, impaired motor skills, paranoia, psychotic symptoms, general apathy, depression and/or restlessness. Marijuana may exacerbate schizophrenia in persons predisposed to that disorder. In addition, the use of medical marijuana may cause me to talk or eat in excess, alter my perception of time and space and impair my judgment. Many medical authorities claim that use of medical marijuana, especially by persons younger than 25, can result in long-term problems with attention, memory, learning, drug abuse, and schizophrenia.

There is substantial evidence of a statistical association between long-term cannabis smoking and worsening respiratory symptoms and more frequent chronic bronchitis episodes. Smoking marijuana is associated with large airway inflammation, increased airway resistance, and lung hyperinflation. Smoking cannabis, much like smoking tobacco, can introduce levels of volatile chemicals and tar in the lungs that may raise concerns about the risk of cancer and lung disease.

_____ I understand that using marijuana while consuming alcohol is not recommended. Additional side effects may become present when using both alcohol and marijuana.

_____ I agree to contact Dr. _____ if I experience any of the side effects listed above, or if I become depressed or psychotic, have suicidal thoughts, or experience crying spells. I will also contact Dr._____if I experience respiratory problems, changes in my normal sleeping patterns, extreme fatigue, increased irritability, or begin to withdraw from my family and/or friends.

f. **The risks, benefits, and drug interactions of marijuana**.

_____ Signs of withdrawal can include: feelings of depression, sadness, irritability, insomnia, restlessness, agitation, loss of appetite, trouble concentrating, sleep disturbances and unusual tiredness.

_____ Symptoms of marijuana overdose include, but are not limited to, nausea, vomiting, hacking cough, disturbances in heart rhythms, numbness in the hands, feet, arms or legs, anxiety attacks and incapacitation. If I experience these symptoms, I agree to contact Dr. _____ immediately or go to the nearest emergency room.

_____ Numerous drugs are known to interact with marijuana and not all drug interactions are known. Some mixtures of medications can lead to serious and even fatal consequences.

I agree to follow the directions of Dr._____regarding the use of prescription and non-prescription medication. I will advise any other of my treating physician(s) of my use of medical marijuana.

_____ Marijuana may increase the risk of bleeding, low blood pressure, elevated blood sugar, liver enzymes, and other bodily systems when taken with herbs and supplements. I agree to contact Dr. _____ immediately or go to the nearest emergency room if these symptoms occur.

_____ I understand that medical marijuana may have serious risks and may cause low birthweight or other abnormalities in babies. I will advise Dr._____if I become pregnant, try to get pregnant, or will be breastfeeding.

g. The current state of research on the efficacy of marijuana to treat the qualifying conditions set forth in this section.

___ Cancer

- There is insufficient evidence to support or refute the conclusion that cannabinoids are an effective treatment for cancers, including glioma.

  There is evidence to suggest that cannabinoids (and the endocannabinoid system more generally) may play a role in the cancer regulation processes. Due to a lack of recent, high quality reviews, a research gap exists concerning the effectiveness of cannabis or cannabinoids in treating cancer in general.

- There is conclusive evidence that oral cannabinoids are effective antiemetics in the treatment of chemotherapy-induced nausea and vomiting.

  There is insufficient evidence to support or refute the conclusion that cannabinoids are an effective treatment for cancer-associated anorexia-cachexia syndrome and anorexia nervosa.

___ Epilepsy

- There is insufficient evidence to support or refute the conclusion that cannabinoids are an effective treatment for epilepsy.

  Recent systematic reviews were unable to identify any randomized controlled trials evaluating the efficacy of cannabinoids for the treatment of epilepsy. Currently available clinical data therefore consist solely of uncontrolled case series, which do not provide high-quality evidence of efficacy. Randomized trials of the efficacy of cannabidiol for different forms of epilepsy have been completed and await publication.

___ Glaucoma

- There is limited evidence that cannabinoids are an ineffective treatment for improving intraocular pressure associated with glaucoma.

  Lower intraocular pressure is a key target for glaucoma treatments. Nonrandomized studies in healthy volunteers and glaucoma patients have shown short-term reductions in intraocular pressure with oral, topical eye drops, and intravenous cannabinoids, suggesting the potential for therapeutic benefit. A good-quality systemic review identified a single small trial that found no effect of two cannabinoids, given as an oromucosal spray, on intraocular pressure. The quality of evidence for the finding of no effect is limited. However, to be effective, treatments targeting lower intraocular pressure must provide continual rather than transient reductions in intraocular

pressure. To date, those studies showing positive effects have shown only short-term benefit on intraocular pressure (hours), suggesting a limited potential for cannabinoids in the treatment of glaucoma.

___ Positive status for human immunodeficiency virus

- There is limited evidence that cannabis and oral cannabinoids are effective in increasing appetite and decreasing weight loss associated with HIV/AIDS.

  There does not appear to be good-quality primary literature that reported on cannabis or cannabinoids as effective treatments for AIDS wasting syndrome.

___ Acquired immune deficiency syndrome

- There is limited evidence that cannabis and oral cannabinoids are effective in increasing appetite and decreasing weight loss associated with HIV/AIDS.

  There does not appear to be good-quality primary literature that reported on cannabis or cannabinoids as effective treatments for AIDS wasting syndrome.

___ Post-traumatic stress disorder

- There is limited evidence (a single, small fair-quality trial) that nabilone is effective for improving symptoms of posttraumatic stress disorder

  A single, small crossover trial suggests potential benefit from the pharmaceutical cannabinoid nabilone. This limited evidence is most applicable to male veterans and contrasts with non-randomized studies showing limited evidence of a statistical association between cannabis use (plant derived forms) and increased severity of posttraumatic stress disorder symptoms among individuals with posttraumatic stress disorder. There are other trials that are in the process of being conducted and if successfully completed, they will add substantially to the knowledge base.

___ Amyotrophic lateral sclerosis

- There is insufficient evidence that cannabinoids are an effective treatment for symptoms associated with amyotrophic lateral sclerosis.

  Two small studies investigated the effect of dronabinol on symptoms associated with ALS. Although there were no differences from placebo in either trial, the sample sizes were small, the duration of the studies was short, and the dose of dronabinol may have been too small to ascertain any activity. The effect of cannabis was not investigated.

___ Crohn's disease

- There is insufficient evidence to support or refute the conclusion that dronabinol is an effective treatment for the symptoms of irritable bowel syndrome.

  Some studies suggest that marijuana in the form of cannabidiol may be beneficial in the treatment of inflammatory bowel diseases, including Crohn's disease.

___ Parkinson's disease

- There is insufficient evidence that cannabinoids are an effective treatment for the motor system symptoms associated with Parkinson's disease or the levodopainduced dyskinesia.

Evidence suggests that the endocannabinoid system plays a meaningful role in certain neurodegenerative processes; thus, it may be useful to determine the efficacy of cannabinoids in treating the symptoms of neurodegenerative diseases. Small trials of oral cannabinoid preparations have demonstrated no benefit compared to a placebo in ameliorating the side effects of Parkinson's disease. A seven-patient trial of nabilone suggested that it improved the dyskinesia associated with levodopa therapy, but the sample size limits the interpretation of the data. An observational study demonstrated improved outcomes, but the lack of a control group and the small sample size are limitations.

___ Multiple sclerosis

- There is substantial evidence that oral cannabinoids are an effective treatment for improving patient-reported multiple sclerosis spasticity symptoms, but limited evidence for an effect on clinician-measured spasticity.

Based on evidence from randomized controlled trials included in systematic reviews, an oral cannabis extract, nabiximols, and orally administered THC are probably effective for reducing patient-reported spasticity scores in patients with MS. The effect appears to be modest. These agents have not consistently demonstrated a benefit on clinician-measured spasticity indices.

___ Medical conditions of same kind or class as or comparable to the above qualifying medical conditions

- The qualifying physician has provided the patient or the patient's parent or legal guardian a summary of the current research on the efficacy of marijuana to treat the patient's medical condition.
- The summary is attached to this informed consent as Addendum_____.

___ Terminal conditions diagnosed by a physician other than the qualified physician issuing the physician certification

- The qualifying physician has provided the patient or the patient's caregiver a summary of the current research on the efficacy of marijuana to treat the patient's terminal condition.
- The summary is attached to this informed consent as Addendum_____.

___ Chronic nonmalignant pain

- There is substantial evidence that cannabis is an effective treatment for chronic pain in adults.

The majority of studies on pain evaluated nabiximols outside the United States. Only a handful of studies have evaluated the use of cannabis in the United
States. and all of them evaluated cannabis in flower form provided by the National Institute on Drug Abuse. In contrast, many of the cannabis products that are sold in state-regulated markets bear little resemblance to the products that are available for research at the federal level in the United States. Pain patients also use topical forms.

While the use of cannabis for the treatment of pain is supported by well controlled clinical trials, very little is known about the efficacy, dose, routes of administration, or side effects of commonly used and commercially available cannabis products in the United States.

h. That the patient's de-identified health information contained in the physician certification and medical marijuana use registry may be used for research purposes.

_____ The Department of Health submits a data set to the Consortium for Medical Marijuana Clinical Outcomes Research for each patient registered in the medical marijuana use registry that includes the patient's qualifying medical condition and the daily dose amount and forms of marijuana certified for the patient.

PART B: Certification for medical marijuana in a smokable marijuana for a patient under 18 with a diagnosed terminal condition.

____ Initial here if you are not a patient under 18 with a diagnosed terminal condition who will be receiving medical marijuana in a smokable form. After initialing here, complete part C.

If the patient is under 18, has a diagnosed terminal condition, and will be receiving medical marijuana in a smokable form, please review and initial the remainder of Part B before completing Part C.

Respiratory Health

____ Exposures to tobacco smoke and household air pollution consistently ranks among the top risk factors not only for respiratory disease burden but also for the global burden of disease. Given the known relations ships between tobacco smoking and multiple respiratory conditions, one could hypothesize that long-term cannabis smoking leads to similar deleterious effects of respiratory health, and some investigators ague that cannabis smoking may be even more harmful that of tobacco smoking. Data collected from 15 volunteers suggest that smoking one cannabis joint can lead to four times the exposure to carbon monoxide and three to five times more tar deposition than smoking a single cigarette.

Cognitive and Psychosocial Development

____ Researchers are still studying the long-term health effects of marijuana. Most people agree that marijuana use hurts adolescents more than adults. It is during the period of adolescence and young adulthood that the neural substrates that underlie the development of cognition are most active. Adolescence marks one of the most impressive stretches of neural and behavioral change with substantial a protracted development in terms of both brain structure and function. As a result, cannabis and other substance use during this period may incur relatively greater interference in neural, social, and academic functioning compared to late developmental periods.

- There is moderate evidence of a statistical association between acute cannabis use and impairment in the cognitive domains of learning, memory, and attention.
- There is limited evidence of a statistical association between sustain abstinence form cannabis use and impairments in the cognitive domains of learning, memory, and attention.

- There is limited evidence of a statistical association between cannabis use and impaired academic achievement and education outcomes.

- There is limited evidence of a statistical association between cannabis use and increased rates of unemployment and/or low income.

- There is limited evidence of a statistical association between cannabis use and impaired social functioning or engagement in developmentally appropriate social roles.

Addiction

Marijuana, like some other brain-altering substances, can be addictive. Nearly one in 10 marijuana users will become addicted. Starting to use marijuana at a younger age can lead to a greater risk of developing a substance use disorder later in life. Adolescents who begin using marijuana before age 18 are four to seven times more likely than adults to develop a marijuana use disorder.

Part C: For certification of smoking marijuana as an appropriate route of administration for a qualified patient, other than a patient diagnosed with a terminal condition

____ **Acknowledgement of contaminant risks.**

Smokable marijuana has infectious risks that are not present in processed products. Certain molds and mildews can contaminate marijuana plants during growing, processing, storage in dispensaries and in patient homes. These contaminates can pose health risks, particularly to those who are immunosuppressed due to their disease state and treatments. While the State of Florida requires third party testing you should still inspect your product.

____ **Respiratory Health.**

Exposures to tobacco smoke and household air pollution consistently ranks among the top risk factors not only for respiratory disease burden but also for the global burden of disease. Given the known relations ships between tobacco smoking and multiple respiratory conditions, one could hypothesize that long-term marijuana smoking leads to similar deleterious effects of respiratory health, and some investigators ague that marijuana smoking may be even more harmful that of tobacco smoking.

_____ **Information regarding health risks of 2nd and 3rd hand smoke to other household members.**

You should never smoke medical marijuana around other family members, especially children and any household guests. You should smoke outside to allow adequate ventilation and to mitigate the dangers of secondhand and thirdhand smoke to others. Marijuana should never be smoked inside vehicles or other small spaces that children will occupy even if the children are not present at the time the product is consumed.

____ **Dangers of smoking marijuana in households where oxygen is in use.**

If you use oxygen or have others in your household who use oxygen you should not smoke marijuana or any other combustible material in the vicinity of where the oxygen is in use due to the risk of fire and explosion.

____ **Self-dosing, if permitted.**

I have been given instructions or discussed guidance on self- dosing with my qualified physician if permitted to do so.

Part D: Must be completed for all medical marijuana patients

_____ I have had the opportunity to discuss these matters with the physician and to ask questions regarding anything I may not understand or that I believe needed to be clarified. I acknowledge that Dr._____has informed me of the nature of a recommended treatment, including but not limited to, any recommendation regarding medical marijuana.

Dr._____also informed me of the risks, complications, and expected benefits of any recommended treatment, including its likelihood of success and failure. I acknowledge that Dr. _____informed me of any alternatives to the recommended treatment, including the alternative of no treatment, and the risks and benefits. Dr. _____ has explained the information in this consent form about the medical use of marijuana.

Patient (print name) _____

Patient signature or signature of the parent or legal guardian if the patient is a minor:

_____ Date _____

I have explained the information in this consent form about the medical use of marijuana to _____ (Print patient name).

Qualified physician signature:

_____ Date _____

Witness:

_____ Date_____

64B8-9.018, F.A.C.
64815-14.013, F.A.C.
DH-MQA-5026 (Rev. 03/21)

GENder Education and Care Interdisciplinary Support (GENECIS)

Puberty Suppression Treatment for Patients with Gender Dysphoria

Patient Information and Informed Parental Consent and Assent for Minors

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

After your questions or concerns are addressed and you have decided to proceed with puberty suppression for your child, you will need to initial the statements of this form as well as sign the consent form. If there is more than one parent/legal guardian, both will have to sign. Your child will also need to assent this form.

What are the benefits of suppressing puberty in adolescents with gender dysphoria?

The Endocrine Society recommends suppression of puberty (put puberty "on hold" with "puberty blockers"), for children that have the diagnosis of gender dysphoria as well as other specific criteria listed in the section below. This recommendation was done by experts in treating youth with gender dysphoria, based on the premise that this may: allow for a smooth social transition to the gender role that is congruent with their gender identity; test persistence of the affirmed gender after living a "real-life experience" and before receiving irreversible hormonal or surgical treatment; and diminish the psychological trauma and risk of suicide induced by the physical changes of puberty.

This may also avoid the need for surgery and other expensive treatments that are required to reverse the physical effects of puberty (i.e. mastectomies, tracheal and facial shaving, and electrolysis).

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

The only 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. No studies have been done comparing psychological therapy only versus suppression of therapy.

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 can be started just after the early physical changes of puberty. None of them 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. However, pediatric endocrinologists (children's doctors who specialize in hormones and puberty), use these medications frequently to suppress puberty in children with precocious (early) puberty.

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, and on a slightly smaller dose, it is approved in adults with prostate cancer under the name of Vantas. 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.

What are the requirements to receive suppression of puberty for gender dysphoria in our program?

In order to receive therapy to put puberty on "hold" at our center, 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 and we want to provide the safest treatment. These requirements will allow us to monitor your child's medical as well as mental health wellbeing during hormone therapy. If these requirements are not met, treatment with puberty blockers may be discontinued in the best interest and safety of your child.

Before beginning treatment with a "puberty blocker" your child needs to undergo a thorough psychological and social evaluation performed by our GENECIS team. 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. Your child will need to have started puberty, which varies from person to person but usually occurs after age 8.

After all this has taken place, treatment to suppress puberty can be initiated if your child meets specific criteria established by the Endocrine Society, which includes ALL of the following:

1. Fulfill the current DSM or ICD criteria for gender dysphoria or transsexualism.
2. Have (early) 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, and sex reassignment surgery, 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.

2. Laboratory testing every 3-4 months.

3. Xray of the hand (bone age) once a year.

4. Bone (dexa) 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.

5. Yearly mental health assessment and completion of questionnaires with a member of our mental health care team. This will allow us to monitor your child's psychological wellbeing and adjustment while on puberty blockers.

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 giving treatment for suppression of puberty to your child.

Effects of Treatment of Suppression of Puberty

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

_____ I know that the effect of this medication is 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 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. At this time, I support my child in "putting on hold" the hormones and the changes induced by puberty.

_____ 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 may not be able to completely prevent serious psychiatric events such as a suicidal attempt.

_____ I know that the treatments to suppress puberty may induce weight gain.

_____ 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.

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 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 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

GENder Education and Care Interdisciplinary Support (GENECIS)

Feminizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Consent and Assent for Minors

Before using medications to transition your adolescent to her/his affirmed gender, you need to be aware of the possible advantages, disadvantages and risks of these medications. We have listed them here for you.

Once your questions or concerns are addressed, and you have decided to proceed with the medication(s), you will need to sign this information and consent form. If there is more than one parent/legal guardian, both will have to sign. 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 "standard of care" as long as they also meet specific criteria listed below, 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 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 women.

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 and mental health effects.

Both these medicines, as well as the process of transitioning can affect your adolescents' mood. While trans women are usually relieved and happy with the changes that occur, 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.

Alternatives

There are alternatives to using feminizing medicines to help people appear more feminine. Some transgender people choose to not take hormones or have surgery and may only socially transition. If you are interested in alternatives, talk with your adolescent's health care provider about options.

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

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 HRT your child needs to undergo a thorough psychological and social evaluation performed by our GENECIS team. 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.

After all this has taken place, HRT can be initiated if your child meets the criteria established by the Endocrine Society, 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 ≥16 years old and has experienced a full social transition to the desired gender for ≥1 year.

OR

8. Your child is 14-15 years of age, has experienced a full social transition to the desired gender for ≥2 years and has been on a puberty blocker for ≥ 1 year.

After HRT 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.

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 (dexa) 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 and completion of questionnaires with a member of our mental health care team. 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.

What are the effects and risks of using these medications?

Estrogen can cause blood clots. We must be careful that your child is not at risk to develop a blood clot. Who should not take estrogen?

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 who

- Has a strong family history of breast cancer or other cancers that grow quicker when estrogens are present
- Has uncontrolled diabetes
- Has heart disease
- Has chronic hepatitis or other liver disease
- Has uncontrolled high cholesterol
- Has migraines or seizures
- Is obese
- Smokes cigarettes

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 your 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 to your 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 with your child's provider. It could be caused by the estrogen or by something else.

- While we do not know the exact risk, the risk of breast cancer may be increased to as high as if your child had been born female.

_____ I know that the following changes are usually not permanent — they are likely to go away 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 may lose muscle and strength in the upper body.
- The skin may become softer.

_____ _____ I know that your 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 down to half their size.
- It is likely that 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 have 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.
- Although these medicines can't make these changes happen, there are other treatments that may be helpful.

____ I know that there may be mood changes with these medicines. I agree to hie my alolescent conti nue therapy with aqualif ied therapist.

____ I know that using these medicines to feminize is an off-Iel 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 your child's health care provider and the best information that is currently iaille in the medical literature.

Risks of Feminizing Medications

____ 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 may not be leto completely prient serious psychiatric ients such as a suicidal attempt.

____ I know that my child should not tce more medicine than prescribed. Tcing too much medication:

- Will increasehealth risks
- Won't make changes happen more quickly or more significantly

_____ I know these medicines may damage the liver and may leJ to liver disease. Therefore, I should be checked for possible liver damage as long as I take them.

____ I know these medicines cause changes that other people will notice. Some transgender people hie experienced discrimination because ofthis. I know my child's clinician can help me find a1vocay and support resources.

Risks of Estrogen

____ I know that tcing estrogen increases the risk of blood clots or problems with blood vessels which are rare in young people but that can result in:

- Chronic problems with veins in the legs
- Heart attk
- 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 your child smokes cigarettes. The danger isso high that your child should stop smoking completely if estrogen is started.

____ ____ I know tci ng estrogen can increase the deposits of fat around internal organs. This can increase the risk for diabetes and heart disease.

____ ____ I know tci ng estrogen can raise blood pressure.

____ ____ I know that tcing estrogen increasesthe risk of getting gallstones, and I should talk our child's clinician 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 mace them worse if your child alreJy has them.

____ ____ I know that it is not yet known if taking estrogen increases the risk of prol ti nomas. These are non-cancerous tumors of the pituitary gland. I know they are not usually life threatening, but they can damage vision and cause heJahes if th' are not treated properly. Therefore, if your child has changes in vision, heJhesthat areworsewhen wcing up in the morning, and milky dischargefrom the nipples, these can be signs of a prolti noma, and I should talk to my child's provider. There is a blood test that can check for this.

Risks of Androgen Antagonists

____ ____ I know that spi ronol atone affects the balance of water and salts in the kidneys This may:

- Increase the amount of urine produced, mcing it necessary to urinate more frequently.
- Increasethirst.
- Increase risk of dehydration (not hiing enough water), and your child should mcesure to drink plenty of water in hot weather.
- Rarely, cause high levelsof potassium inthe blood, which can causechanges in heart rhythms that may be life threatening. Your child's doctor will perform a blood test to monitor this risk while on the medication.
- Reduce blood pressure.

Requirements for HIRT at the GENECIS program:

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 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 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 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.

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

Testosterone Treatment for Patients with Gender Dysphoria

Patient Information and Informed Consent and Assent for Minors

Before using testosterone to transition and masculinize your adolescent's body, you need to be aware the possible advantages, disadvantages and risks. We have listed them here for you. It's important that you understand all of this information before you agree to having your adolescent begin taking testosterone.

Once your questions or concerns are addressed, and you have decided to proceed with the testosterone treatment, you will need to sign this information and consent form. If there is more than one parent/legal guardian, both will have to sign. Your child will also need to assent this form.

What is testosterone and why is it used in people with gender dysphoria?

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 considered "standard of care" as long as they also meet specific criteria listed below, but these medications do not have the FDA indication to be used in this population, in other words, it is "off label use".

Alternatives

There are alternatives to using HRT to help people appear more male. Some transgender people choose to not take hormones or have surgery and may only socially transition. If you are interested in alternatives, talk with your adolescent's health care provider about options.

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. While trans men are usually relieved and happy with the changes that occur, it is important you're 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 our program?

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 HRT your child needs to undergo a thorough psychological and social evaluation performed by our GENECIS team. 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.

After all this has taken place, HRT can be initiated if your child meets the criteria established by the Endocrine Society, 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 ≥16 years old and has experienced a full social transition to the desired gender for ≥1 year.

OR

8. Your child is 14-15 years of age, has experienced a full social transition to the desired gender for ≥2 years and has been on a puberty blocker for ≥ 1 year.

9. After HRT has been initiated, 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 (dexa) 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. Mental health assessments and completion of questionnaires with a member of our mental health care team every 3 months. 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

Warning 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

BENEFITS	RISKS
• Appearing more like a man ○ Bigger clitoris ○ Coarser skin ○ Lower voice ○ More body hair ○ More facial hair ○ More muscle mass ○ More strength ○ No more menstrual periods • More physical energy • More sex drive • Protection against bone thinning (osteoporosis)	• Acne (may permanently scar) • Blood clots (thrombophlebitis), risk significantly increased by smoking • Emotional changes, for example, more aggression • Headache • High blood pressure (hypertension) • Increased red-blood-cell count • Infertility • Inflamed liver • Interaction with drugs for diabetes and blood thinning – for example Coumadin and Warfarin • Male pattern baldness

	• More abdominal fat — redistributed to a male shape • More risk of heart disease • Swelling of hands, feet, and legs • Weight gain

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

Masculinizing Effects

_____ _____ I know that testosterone may be prescribed to make your 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 are likely and 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 are usually not permanent — they are likely to go away 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 the effects of testosterone on fertility are unknown. I hie been told* that your child may or may not be leto get pregnant even if testosterone is discontinued. I know that your child may still get pregnant even after testosteronestops menstrual periods

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

- Losing some fat may me breasts appear slightly smaller (if present), but th' will not shrink very much.
- The voice will deepen, but other aspects of the way your alolescent spes may not sound more masculine.
- Although testosterone can't make these changes happen, there are other treatments that may be helpful.

____ ____ *I know that there may be mood changes with these medicines. I agree to hie my* child continuetherapy with aquified therapist.

_____ I know that using testosterone is an off-lel use in this population. 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 your child's health care provider and the best information that is currently availle in the medical literature.

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 realize that thistreatment may not beleto completely prevent serious psychiatric events such as a suicidal attempt.

____ ____ *I know that your child should not te more testosteronethan prescribed. Tdng* 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 in Julthood. These changes include hiing:

- Less good cholesterol (HDL) that may protect against heart disease and more bal 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 leal to liver disease and your child should bechecked for possible liver damagewhiletdng testosterone.

____ ____ I know testosteronecan increase red blood cells and hemoglobin. This increase is usually only to what is normal for a man and shouldn't cause any health risks. However, there is a small possi bility that higher lielsof red blood cells and hemoglobin may increase my risk of life-threatening problems such as stroke or heart attack. That's why I know your child will need periodic blood checks while testosterone.

___ ___ I know that td ng testosterone can increase the risk for dietes. It may decrease the body's response to insulin, cause weight gain, and increase deposits of fat around internal organs Therefore, your child should hie periodic checks of my blood glucose while td ng testosterone.

____ ____ I know that testosterone can give heJhes or migraines. I know that it's best to talk with your child's clinician if migraines occur often or if the pain is unusually severe.

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

___ ___ I know that testosterone causes changes that other people will notice. Some transgender people hie experienced harassment, discrimination, and violence because of this.

Requirements for HIRT at the GENECIS program:

____ I understand and agree with all the requirements explained ove, in order to receive HRT in our program.

_____ I know that the mental heath 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 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 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 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.

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 taking testosterone.

_____ _____ I do not wish my adolescent to begin taking testosterone 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 testosterone with my parent(s) or legal guardian(s), and I wish to receive it.

Minor's Name (printed)

Minor's Signature Date

INFORMED CONSENT FORM
ESTROGEN THERAPY FOR GENDER DYSPHORIA

The cause of gender dysphoria is not known, but is thought to be partly due to genetic or environmental causes affecting the early development of my brain pathways. I understand that the effect of this on me means that, even though I think of myself partially or completely as female, I am genetically, biologically and physically male. I want to receive treatment that will help me change my body towards that of a female, so that it will match my sense of myself (my gender identity).

With the understanding and consent of my parents/guardians, I may have been taking a medicine called Lupron Depot@ to stop me from going through puberty as a male. I may also have been taking an anti-androgen medication called spironolactone to prevent beard growth. Regardless, my treatment also involves "talking therapy" (psychotherapy) to help me think about all the possible results and consequences of going part or all the way through the physical change, called "transition", from a male towards a female body.

I understand that I may now begin taking the female hormone estrogen, up to a dose that would be normal for females my age. I understand that estrogen will cause my body to become more feminine in appearance, and it will reduce my male hormones. I know that this treatment will not change my genetic sex (chromosomes), and it will not change my external genitals (penis and testicles).

I understand that, although estrogen is a common treatment for adults with gender dysphoria, using this treatment in young adolescents is a newer development, and the long-term effects are not fully known. It has been explained to me that doctors are prescribing estrogen because they believe that I will continue towards full or partial physical transition to a female body, perhaps including eventual surgery to remove or reshape my external male genitals. However, taking estrogen now does not guarantee that I will eventually want, need, or have this surgery. Gender-affirming surgery has to be talked about in detail when I am further along in my transition, and final decisions can only be made after I have been living in the gender role that is congruent with my gender identity for a period of time.

There are also possible long-term considerations and risks of estrogen use in natal males, as follows:

1. The feminizing effects of estrogen can take several months or longer to become noticeable, and that the rate and degree of change can't be completely predicted, and changes may not be complete for 2-5 years after starting estrogen.

2. Taking estrogen will cause breast development:
   - Breasts may take several years to develop to their full size.
   - Even if estrogen is stopped, the breast tissue that has developed will remain.
   - As soon as breasts start growing, it is recommended to start doing monthly breast self-examinations and to have an annual breast exam by a doctor or nurse.
   - There may be milky nipple discharge (galactorrhea). This can be caused by taking estrogen or by an underlying medical condition. It is advised to check with a doctor to determine the cause.
   - It is thought that taking estrogen can increase the risk of breast cancer to that of non-trans women.

3. The following changes are generally not permanent (that is, they will likely reverse if estrogen is discontinued):
   - Skin may become softer.
   - Muscle mass decreases and there may be a decrease in upper body strength.