

## **INFORMED CONSENT FORM LUPRON DEPOT® FOR NATAL MALES WITH GENDER DYSPHORIA**

I am receiving treatment 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 my body stop having the changes of male puberty, so that it will help to match my sense of myself (my gender identity). This will allow me time to continue my gender journey without having to worry about unwanted, permanent body changes.

With the understanding and consent of my parents/guardians, I will start taking Lupron Depot®, a type of medication called a gonadotropin-releasing hormone analog, to stop my body from going through the changes of male puberty. At the same time, 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 while Lupron Depot® treatment will reduce my male hormones and prevent further male body changes, it will not make my body more feminine. 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 Lupron Depot® is a common treatment for children with precocious puberty, it is newer to being used in healthy young adolescents with gender dysphoria, and the long-term effects are not fully known. It has been explained to me that my doctors are suggesting and prescribing Lupron Depot® because they believe that this will allow me more time to explore my gender and other developmental issues. This may also facilitate my later physical transition by preventing the development of male sex characteristics (such as broad shoulders, large Adam’s apple, or a beard) that are difficult or impossible to reverse if I continue on to pursue gender-affirming surgery. I may (or may not) decide down the road for partial or full physical transition to a female, perhaps including eventual estrogen therapy to cause female body changes and surgery to remove or reshape my external male genitals. However, taking Lupron Depot® now does not guarantee that I will eventually want, need, or have estrogen therapy and/or surgery. The decision to start estrogen therapy will be made jointly between me, my parents or caregivers, and my medical and mental-health doctors. 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 short- and long-term considerations and risks of Lupron Depot® use in natal males, as follows:

1. Lupron Depot® is not generally started in youth until their gender dysphoria has emerged or worsened with the earliest signs of puberty (called Tanner stage 2). In natal males, this means enlargement of the testicles. As well, any co-existing psychological, medical, or social problems that could interfere with treatment must have been addressed prior to starting.
2. Lupron Depot® is given as an intramuscular (deep) injection in the thigh every 4 weeks; longer-acting forms can be given every 13 weeks. This can be given by the family doctor or a trained family member. The injections do cause some pain.
3. When patients take Lupron Depot, they need to have regular blood testing (generally, after 3 months, and then every 6–12 months), to ensure that the dosage of Lupron Depot® is correct. This may involve a 45-minute test with an IV.
4. In general, Lupron Depot® therapy is continued no longer than two years without stopping or adding in estrogen therapy.

***Informed Consent Form: Lupron Depot® for Natal Males with Gender Dysphoria (continued)***

5. If Lupron Depot® is not taken regularly as directed, it can actually cause a speeding-up of pubertal changes.
6. Lupron Depot® works fairly rapidly to reduce the testosterone to a very low level. This will halt the physical changes of male puberty, such as enlargement of the testicles and penis; development of muscles; development of pubic, armpit and facial hair; lowering of the voice; broadening of the shoulders and widening of the jaw; development of a male Adam's apple; sex drive, erections and ejaculations (wet dreams).
7. Lupron Depot® will not reverse some of the changes of male development that have already happened (Adam's apple, voice changes, shoulder and jaw bone changes, and penis size). It will cause a decrease in testicular size, body hair and muscle development. It will reduce the sex drive and ability to have erections and ejaculations.
8. While Lupron Depot® interferes with fertility, it does not affect the ability to get a sexually transmitted infection. Precautions against getting an STI must still be taken.
9. When Lupron Depot® is stopped, it is known that the puberty restarts within 3–6 months. To the best of our knowledge, there are no permanent effects on male fertility or testicular health if the Lupron Depot® is taken and stopped.
10. If Lupron Depot® is taken during the growth spurt, it will slow down the growth rate. In natal males, this may cause an overall slight decrease in the adult height, particularly if they later start on estrogen.
11. Lupron Depot® causes the calcium uptake by the bones, which is greatly increased during puberty, to slow down. For this reason, it is important that patients on Lupron Depot® take other measures to protect their bones: keeping active and ensuring good calcium and Vitamin D intake. It is not known if using Lupron Depot® increases the chance for osteoporosis in older age.
12. There is about a 5% (1 in 20) chance that a person taking Lupron Depot® can develop an allergy to the medication, which presents as a red, painful sterile abscess (boil) at the injection site. This may start out gradually and get worse with each injection. Rarely, the abscess will have to be drained by incision. If a person develops this problem, the Lupron Depot® must be stopped, and there may not be an alternate medication.
13. There may be long-term side-effects of Lupron Depot® that we do not yet know about.

I agree to take Lupron Depot® as prescribed and to tell my doctor if I am not happy with the treatment or am experiencing any problems. I understand that the right dose or type of medication prescribed for me may not be the same as for someone else. I understand that physical examinations and blood tests are needed on a regular basis to check for the effects of Lupron Depot®. I understand that Lupron Depot® can interact with other medications, dietary supplements, herbs, alcohol, and street drugs. I understand that being honest with my care provider about what else I am taking will help prevent medical complications that could be serious. I have been informed that I will continue to get medical care no matter what information I share. I understand that I can choose to stop taking Lupron Depot® at any time, and that it is advised that I do this with the help of my doctor to make sure there are no negative reactions to stopping. I understand that my doctor may suggest I stop taking Lupron Depot®, if there are severe side effects or health risks that can't be controlled.

