

This is a record of the informed consent process for:

Name:.....  
Date of Birth:...../...../..... RiO:.....

## **Information about treatment with Testosterone**

**(For the purpose of making a declaration of consent to treatment)**

### **What is testosterone?**

Testosterone is a hormone medication which can help you to masculinise (develop a more masculine body type) and reduce some more feminine aspects of your body. Before taking the medicine, there are several things you need to know. These are the possible advantages, disadvantages, risks, and warning signs, as is the case with any medicine that you take. We have listed them here for you. It's important that you understand all of this information before you start taking the medicine so that you can make a decision about whether or not this is the right medicine for you. We are happy to answer any questions you have.

### **How is testosterone taken?**

Testosterone can be taken in different ways.

- An injection into a muscle (intramuscular injection)
- A gel applied to the skin (transdermal application)

The way that you take the testosterone can affect how quickly the changes happen in your body. Over time you will have the same amount of body changes whether you choose to use gel or injection. If you want or need to, we can offer you a dose of testosterone gel which can cause the changes to happen more slowly than injected testosterone for most people. However, for some people there is no difference between using gel or having injections of testosterone in how quickly the changes happen.

### **Managing Change**

Some people prefer that they manage the rate of change in their body more slowly. If you feel that managing changes is important to you, you can speak to your doctor about using smaller gel doses to bring about changes more slowly.

### **Who is at higher risk of health problems if they take testosterone?**

***Testosterone must not be used by anyone who is, or is planning to become, pregnant. If you are thinking of becoming pregnant, please discuss this with us. You should take a pregnancy test before starting treatment with testosterone if there is any chance at all that you could be pregnant***

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

- has angina (cardiac chest pain on exertion) or uncontrolled cardiac disease
- has breast cancer or other cancers that grow quicker when oestrogens are present
- has a family history of heart disease or breast cancer
- has had a blood clot (thrombosis, pulmonary embolism) or stroke
- has high levels of cholesterol
- has liver disease
- has a high red-blood-cell count (also known as polycythaemia or erythrocytosis)

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- has acne
- is obese
- uses nicotine, especially in the form of cigarettes

Periodic blood tests will be needed to check levels and effects of the testosterone. Breast examinations, mammograms and cervical smear tests may still be recommended by your doctor in line with the national screening guidelines.

### What testosterone does to your body

The effects of testosterone vary from person to person, so this is just a rough idea of timescales, which can also be affected by whether you are taking testosterone treatment as an injection or gel.

Effect of Testosterone	Expected start of effect	Expected end of changes
Increased sex drive	1-3 months	
Vaginal dryness and thinning of vaginal walls	1-6 months	1-2 years
Oilier skin and acne (spots on face, neck and back)	1-6 months	1-2 years
Increase in amount and thickness of hair on body	1-3 months	3-5 years
Increase in amount and thickness of facial hair	6-12 months	4 years
Clitoris growth (on average by about 1-3 cm)	3-6 months	1-2 years
Body fat moves generally from hips and thighs to tummy	3-6 months	2-5 years
Menstrual period bleeding stops	up to 6 months	
More red blood cells are made	3-6 months	
Voice deepens	6-12 months	2 years
Increase in size and strength of muscles	6-12 months	2-5 years
Head hair loss	12 months	variable

### How permanent are the effects of Testosterone?

Most of the noticeable changes caused by taking testosterone are NOT fully reversible *even if you stop taking testosterone*.

- Most voice deepening and head hair loss is usually permanent
- Clitoris growth and body and facial hair changes will decrease but will not usually return to the original appearance
- Menstrual periods will usually return, unless you have reached the menopause and fat, muscle and skin changes will reverse.
- Infertility- The long term effects of testosterone are not fully understood and the ability for your ovaries to produce eggs may not come back even if you stop taking it. *i.e.* you may not be able to become pregnant if you stop taking testosterone.

If you decide you are unhappy with the effects of testosterone and no longer wish to take it, the NHS is unlikely to provide treatment to reverse changes that have already occurred.

It is important to recognise that for some people their current gender identity is not permanent. It may be that your gender identity changes in the future and you might not be happy with the permanent changes to your body caused by taking testosterone.

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### **The effects of prescribed testosterone that are not fully reversible**

- I know that testosterone may help me appear less feminine and/or more masculine.
- 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 my facial and body hair may increase and that if I stop taking testosterone this will not continue to increase but it may not return to the way that it was originally. Treatment to reduce body or facial hair may not be available on the NHS.
- I know that my voice may deepen and that it will not return to the original pitch if I stop taking testosterone
- I know that my clitoris may become enlarged and that if I stop taking testosterone it will not return to the original size.
- I know that, if I develop male pattern head hair loss, it is very unlikely that any hair that has been lost will grow back

### **The effect of testosterone on fertility**

- The long term effects of testosterone on fertility are not fully understood. You might become permanently sterile, in other words, you may not be able to get pregnant even if you stop taking testosterone.
- I know that my body will make less oestrogen and progesterone. This may affect my sex life in different ways and my fertility:
  - Taking testosterone is not a form of contraception. I know that I might get pregnant if I have vaginal intercourse or other intimate sexual contact without contraception.
  - I know that I may have more sex drive but also experience vaginal dryness.
  - Getting pregnant whilst taking testosterone can cause the developing baby to be damaged by the testosterone, this is called a teratogenic effect.
  - The options for storing of eggs, to preserve my fertility, have been explained to me
  - Testosterone does not protect me from HIV or sexual infections and I should use protective contraception as usual.

### **The reversible effects of testosterone on the body**

- I know that the following changes are usually not permanent and are likely to gradually go away if I stop taking testosterone.
  - I know I will probably have more fat on my abdomen and less on my buttocks, hips, and thighs. It will be redistributed to a more masculine/less feminine shape.
  - I know I may gain muscle mass and strength in my upper body
  - I know that my skin may become coarser and more oily and that I might have acne.
  - I know that my menstrual periods may slowly lessen and stop and that if I stop taking testosterone the time that it takes for them to return is uncertain.

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- I know that the number of my red blood cells may increase and that this might make my blood more sticky which might increase my risk of developing blood clots.

I know that testosterone can cause or worsen headaches and migraines

I know that some people can experience changes in their mood states such as increased irritability, frustration and anger. However, I know that if my gender dysphoria decreases because of treatment with testosterone, I may have an improvement in my emotional state and sense of general wellbeing.

### **Menstruation**

I know that testosterone can stop menstruation but that if my menstrual periods don't stop then I can discuss a range of other options to stop menstruation with my doctor, if that is important to me.

If your periods (menstrual bleeding) persist despite using testosterone therapy, drugs called gonadotropin releasing-hormone analogues (GnRHA) can be used to suppress them. These drugs are given by injection every one, three or six months, depending on the preparation used. They overwhelm and then "switch off" the control mechanism of the menstrual cycle that is co-ordinated through your hypothalamus and pituitary gland.

### **What testosterone can't change**

I know that some parts of my body may not change by using this treatment.

- Testosterone will not change my bones, my height, my genes, my internal organs, my breasts or change my genitals into a penis.
- Testosterone is unlikely to change any body image problems that I may have that are not related to gender dysphoria.

I know that some parts of my life will not change by using this treatment

- Taking testosterone will not make me into a different person
- Although taking testosterone can reduce feelings of gender dysphoria for some people, it will not directly improve mental health problems such as depression if they are unrelated to gender dysphoria.
- Taking testosterone won't mean that I find a place in a community or am accepted by everyone.
- Testosterone will not remove all aspects of my body that I experience as feminine.

If you are experiencing difficulties with these areas you may wish to speak to your Gender Clinic or G.P. about them.

### **Risks of Testosterone**

I know that the side-effects and safety of my treatment are not completely known. There may be long-term risks that are not yet known.

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I know I must not take more testosterone than prescribed, as this will increase health risks and won't make changes happen any more quickly or more profoundly. I know that my body can convert excess testosterone into oestrogen, which can in turn slow down or stop my appearing more masculine.

I know that testosterone may cause changes that might increase my risk of heart disease. I know these changes include having:

- less good cholesterol (HDL) that may protect against heart disease and more bad cholesterol (LDL) that may increase the risk of heart disease
- higher blood pressure
- increased risk of abdominal (central) obesity

I know that my risk of heart disease is higher if people in my family have had heart disease, if I am overweight, or if I smoke.

I know that I should have periodic blood pressure and weight checks, typically every year, for as long as I take testosterone.

I know that I should have my cholesterol level checked by my GP from time to time.

I know that testosterone can cause weight gain.

I know testosterone can increase my red blood cell production and that this can increase my risk of having a blood clot, stroke or heart attack. I know I need to have blood tests with my GP for haematocrit (the proportion of your blood that is composed of blood cells, rather than plasma) every few months when I first start treatment and then once a year, for as long as I take testosterone.

I know that my risk of cancers of the breast is not known with certainty and I may still be at risk of breast cancer after chest surgery. After surgery, I should aim to be "chest aware" (know what my chest looks and feels like) and report any changes to my GP.

I know that my risk of cancers of the ovaries or uterus might be slightly increased but the evidence available is very unclear and it is not possible to recommend treatment based on this evidence. You can discuss this with your doctor.

I know that it is important for me to have cervical screening in line with national screening guidance. I am aware that taking testosterone increases the risk of having cell changes in the cervix identified by this screening process.

I know taking testosterone can thin the tissue of my cervix and the walls of my vagina. This can lead to tears or abrasions during vaginal sex play. This raises my risk of getting a sexually-transmitted infection, including HIV. I know I should speak honestly with my GP or clinician about my sex life, to learn the best ways to prevent and check for infections.

I know that testosterone can cause changes to my body that may cause me to feel more gender dysphoria for some parts of my body.

I know that testosterone causes changes that other people will notice. Some transgender people have experienced harassment, discrimination, and violence because of this. Others have lost the support of loved ones. I know my clinician can help me find advocacy and support resources.

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I know that for some people their current gender identity is not permanent. It may be that my gender identity changes in the future and I might not be happy with the permanent changes to my body caused by taking testosterone.

### **Prevention of Medical Complications**

I know that I must use my treatment at the time and at the dose recommended by my doctor, and I should tell my clinic doctor or GP if I have any problems, side-effects or am unhappy with the treatment.

I know that the dose and type of medication that's prescribed for me may not be the same as someone else's.

I know I need periodic blood pressure and weight measurements, and blood tests to check for unwanted side effects.

I know that testosterone can interact with other drugs and medicines, including alcohol, diet supplements, herbal treatments, other hormones, and street drugs. This kind of interaction can cause complications that can occasionally be life-threatening. I know that I need to be honest with my clinician about whatever else I take. I also know that I will continue to get medical care here no matter what I share about what I take.

I know that my risk of medical problems can increase if I have other medical conditions and take testosterone. I agree to discuss with my clinician if I know of any medical conditions and to tell them if I am given a new diagnosis.

I know that if I have a serious medical event, such as a heart attack, stroke, blood clot or an extremely high number of red blood cells (called polycythaemia or erythrocytosis), I must contact the NRGDS, or ask my GP to do so, so that I can be supported in conversations about how to get the hormone treatment that I need.

I know that using testosterone during pregnancy poses a serious risk to the health of an unborn child and that I must not become pregnant when using it. I also know that it may take several weeks for the testosterone level in my blood to fall to levels that are safe for an unborn child, particularly with long-acting injections such as Nebido.

I know that using most of these drugs to promote masculinising body changes is an off-license use that is not approved by the UK medicines regulatory authority for this purpose. I know that the medicine and dose that is recommended for me is based on currently available research evidence, clinical guidelines, and the judgment and experience of my clinician.

I know that I can choose to stop taking testosterone at any time. I know that if I decide to do that, I should do it with the help of my clinician. This will help me make sure there are no negative reactions. I also know my clinician may suggest that I cut the dose or stop taking it at all if the side effects are severe or there are health risks that can't be controlled.

### **More information**

I know that I can obtain clarification or more information about any aspect of my treatment from the clinical team at NRGDS.

### **Statements**

I have read and understood this information sheet and have no other questions about my treatment

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- I need help with losing weight
- I need help with stopping smoking
- I need help with alcohol or substance use
- I need advice about sexual health
- I need more information about ....

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I confirm that I have had the treatment fully explained to me and have had the opportunity to ask questions. My attention has been drawn to the potential side effects, and I understand that if I experience any of these side effects I must seek advice.

I have agreed that I will only take hormone treatment as prescribed by or recommended by the Gender Identity Service, and that I will avoid using any other hormone treatments.

I know that for some people their gender identity may change over time. It may be that my gender identity changes in the future and I am not satisfied with the irreversible changes to my body caused by testosterone. I understand that it is impossible for me, or anyone else, to predict the future wishes of others with total accuracy. I am willing to consent to taking testosterone under these circumstances.

I understand that I can withdraw from this treatment at any time. If I do so I will inform my doctor.

Signed..... Date:.....

**For staff to complete**

I am satisfied that ..... understands the nature of the proposed treatment and has a full appreciation of the consequences of both the treatment in terms of benefits and possible side-effects and also the possible consequences of not undergoing this treatment. They have retained the information contained within this form and are able to communicate their decision to me today.

Signed..... Date:.....

Clinician name..... Clinical Role.....