ETSUHealth

Patient Informed Consent to Testosterone Treatment

Patient Printed Name:	_____	Patient DOB:	_____
Provider Printed Name:	_____		

Thank you for choosing East Tennessee State University, Medical Education Assistance Corporation, or the Northeast Tennessee Community Health Centers, Inc. (hereinafter referred to collectively as "ETSU Health") for your care. ***Please read this Informed Consent document carefully and ask your provider if you have any questions.***

I understand that my provider is recommending testosterone, which is a controlled substance, to treat (Please circle):

Low testosterone Other condition: (Please list) _____

Note for patients: I understand that a controlled medication is being recommended for me based on the above clinical indication.

This Informed Consent explains the possible risks and the expected benefits of taking testosterone. This Informed Consent also explains what I should expect when taking this type of medication and the possible side effects.

Using Controlled Medications to Treat Medical Conditions:

- Testosterone may be used to treat low testosterone and other medical conditions.
- Testosterone may be used to treat anxiety and stress associated with the above.
- Testosterone may improve function and quality of life.
- Testosterone will not necessarily cure my underlying medical condition or injury.
- Testosterone works differently for different people. Side effects and complications will be different for different people. I understand that I must tell my provider about all medications I am taking. Other medications have interactions with Testosterone that may cause side effects, complications, or make my medication more or less effective.

Common Side Effects – Testosterone: Elevations in blood pressure, which can increase risk of heart attack, stroke, and death; elevated hemoglobin and hematocrit (also known as "blood counts"), which can increase risk of blood clots or ischemia; possibly increase risk of enlarged prostate and cancer; injection site irritation; infertility or other reproductive side effects, either of which may be irreversible; virilization of partners or children.
Less Common Side Effects – Testosterone: Breast cancer; liver damage, including cancer; worsening depression or suicidal ideation; migraines; autoimmune disease; serious allergic reaction.

If you are also using other controlled substances, please be aware of the following side effects:
Common Side Effects – Opioids: Constipation; dry mouth; sweating; nausea; sleepiness; extreme happiness; forgetfulness; trouble urinating; and itching
Less Common Side Effects – Opioids: Confusion; hallucinations; shortness of breath; depression; lack of motivation

Common Side Effects – Benzodiazepines: Clumsiness or unsteadiness; dizziness or lightheadedness; sleepiness; slurred speech
Less Common Side Effects – Benzodiazepines: Anxiety; confusion (may be more common for older people); fast, pounding, or irregular heartbeat; depression; stomach cramps or pain; blurred vision or other changes in vision; changes in sexual desire or ability; constipation; diarrhea; dry mouth; increased thirst; false sense of well-being; headache; watering of mouth; muscle spasm; nausea or vomiting; problems with urination; trembling or shaking; unusual tiredness or weakness.

Common Side Effects – Stimulants: Decreased appetite; weight loss; trouble sleeping; abdominal pain; headache.
Less Common Side Effects – Stimulants: Tics; compulsive behaviors; reduction in seizure threshold; agitation; anxiety; lack of interest.

Dependency:

- Testosterone may be habit-forming (causing psychological dependence).

If you are also using other controlled substances, please be aware of the following:

- Opioids will cause a physical dependency marked by withdrawal symptoms when they are stopped too quickly. If these medications are stopped or rapidly decreased you will experience chills; goose bumps; excessive sweating; increased pain; irritability; anxiety; agitation; and diarrhea. The medicines will not cause these symptoms if taken as prescribed. Any decision to stop these medications should be done under the supervision of your provider by slowly decreasing the dosage except to discontinue the medication in the event of allergic reaction.
- Benzodiazepines may be habit-forming (causing mental or physical dependence). This is especially true when taken for a long time or in high doses. Some signs of dependence on benzodiazepines are: a strong desire or need to continue taking the medicine or a need to increase the dose to feel the same effect of the medicine. Others signs of dependence might include: irritability; nervousness; trouble sleeping; stomach cramps; trembling or shaking.

Addiction: Misusing a controlled substance can cause serious long term negative health effects. Some people experience a "high" from misuse or excessive use. Misuse can also increase a person's risk for serious, immediate medical complications, such as overdose. When someone misuses a controlled substance over and over again, they can lose control over this use. This loss of control is often referred to as "addiction," and is also known as substance use disorder.

Diversion: It is against the law to share your controlled medications with other people. It is against the law to provide false information to your provider to try and obtain controlled medication. It is against the law to visit multiple doctors to try and obtain controlled medications. It is very important that you guard your controlled medications and use them only as prescribed by your provider.

Common Sense Rules for Using Controlled Medications:

- Follow your provider's recommendations.
- Do not take more or less pills/injections or apply more topical testosterone than prescribed without discussing this first with your provider and receiving permission to do so.
- Do not share medications with family or friends.
- Do not take medications from family or friends.
- Do not stop medications quickly. Dose reductions need to be discussed and okayed by your provider. This is important no matter which controlled medication you take.
- Do not sell medications.
- Keep all medications out of reach of children.
- Do not leave your prescriptions or controlled medications lying around unprotected for others to steal and abuse them.
- Do not use illegal substances.

For People of Childbearing Age with Reproductive Capacity (under Tennessee law ages 15-44): It has been explained to me that the use of testosterone/narcotic/opioid medication poses special risks to people who are pregnant or may become pregnant. I have been advised that if I become pregnant, I need to stop taking testosterone. I have also been advised that I should not take testosterone while breastfeeding. Potential adverse effects include, but are not limited to: virilization of the fetus/baby, suppression of breastmilk production. I also understand that **birth defects** can occur in any baby whether or not they are exposed to medications in utero. I recognize that the long-term consequences on a child's development who was exposed to controlled substances, including testosterone, is not fully understood and cannot be predicted, but it could be harmful to the child.

Birth control counseling:

I have been informed of the birth control (or contraceptive) options available to me. I understand that birth control can reduce the chances that I become pregnant while being treated with testosterone medication. I have been counseled on appropriate and effective forms of birth control. I have also received information about how I can receive free or reduced cost birth control. ***If I plan to become pregnant or believe that I have become pregnant while taking testosterone, I will immediately inform my provider.***

I understand continuation and any dose changes of controlled medications will be determined by my provider. This will be based on how the medication is helping me manage my medical conditions and whether or not the expected benefits outweigh the risks.

I understand my provider may discontinue treating me at their discretion. They may require more frequent visits.

ETSU Health believes in treating your low testosterone or other related conditions and we recognize the value of testosterone in this process. When used properly, controlled medications can help improve comfort, function, and quality of life. However, as stated above, controlled medications may also have serious side effects and are controlled because of their potential for misuse and abuse. It is important that we work together and communicate openly and honestly.

By signing below, I confirm that I have read and understand this Informed Consent document, and that I had the opportunity to have this Informed Consent document explained to me. I confirm that I have had the opportunity to ask questions and that all my questions have been answered. I understand that treatment that includes controlled medications is not the only option to treat my condition or symptoms, and the benefits and risks of alternative treatments (including declining treatment) have been explained to me. By signing below, I confirm that I have enough information to make a decision to use the controlled medications prescribed.

You should NOT sign this form if you do not believe you have enough information to make an informed decision about your use of controlled medications and how they fit in to your pain management treatment plan.

Patient/LAR Signature:	_____	Date:	_____
Provider Signature:	_____	Date:	_____
Witness Signature:	_____	Date:	_____

If signed by someone other than the Patient, state your relationship to the Patient and a description of your authority to act on the Patient's behalf:

_____.

ETSUHealth

Patient Agreement to Testosterone Treatment

Patient Printed Name:	_____	Patient DOB:	_____
Provider Printed Name:	_____		

Please read this Agreement carefully, and ask your provider if you have any questions.

This Agreement between myself and East Tennessee State University, Medical Education Assistance Corporation, or the Northeast Tennessee Community Health Centers, Inc. (hereinafter referred to collectively as "ETSU Health"), is intended to provide important information about the use of controlled substances to help manage my low testosterone or other related conditions.

I understand that there are side effects to this treatment. Some of these side effects are: elevations in blood pressure; elevated hemoglobin and hematocrit (also known as "blood counts"), which can increase risk of blood clots or ischemia; possibly increase risk of enlarged prostate and cancer; injection site irritation; infertility or other reproductive side effects, either of which may be irreversible; virilization of partners or children; breast cancer; liver damage, including cancer; worsening depression or suicidal ideation; migraine; autoimmune disease; serious allergic reaction. When testosterone is used long-term, other concerns include the development of psychological dependence. I understand these risks and have discussed them with my provider.

I understand that ETSU Health will prescribe controlled substances only if the following terms are adhered to:

1. It is deemed clinically appropriate and the benefits continue to outweigh the risks.
2. I understand it is against the law to provide false information to my provider to try to obtain controlled substances. I understand it is against the law to visit multiple doctors to try to obtain the same controlled substances.
3. I will submit urine and/or blood on request for testing at any time, without prior notice. These tests will be used to detect the use of non-prescribed drugs, including illegal substances, and medications and confirm appropriate use of those that are prescribed. I will bring my medications to each appointment. I will pay any portion of the costs that result from urine and blood testing that is not covered by my insurance.
4. I will fill my controlled substance prescriptions at one pharmacy. This pharmacy is authorized to release a record of my medications to this office upon request.

   The pharmacy that I have selected is: _____
   The pharmacy phone number is: _____

5. I understand an office appointment with my provider is necessary to obtain refills for controlled substance prescriptions. I understand that if I take my medications more often than prescribed then I will "run out" early. If this happens my medications will <u>not</u> be filled early. I understand that it is my responsibility to ensure that I leave the office with an appointment consistent with my medication supply. I understand that if I need to call in to make an appointment for a refill, I will give my provider <u>at least</u> three business days' notice. Accidental destruction, loss of medications or prescriptions will not be a reason to refill medications or rewrite prescriptions early. Controlled substances will not be filled after hours or on the weekends.
6. I will guard my controlled substance medications from use by family members, children or other persons. I understand it is against the law to share my medications with others.
7. I understand that I must take my medication only as prescribed and only as a part of a comprehensive treatment plan to manage my conditions. I will not change the amount or dosage frequency without prior approval from my provider except to discontinue the medication in the event of an allergic reaction.
8. I understand that I must tell my provider about all other medications, including over the counter treatments that I am

taking. I understand I must immediately inform ETSU Health of any new medications or treatments.

9. **For People of Childbearing Age with Reproductive Capacity (under Tennessee law ages 15-44):** If I plan to become pregnant or believe that I have become pregnant while taking testosterone, I will immediately inform ETSU Health. I understand that these medications may cause harm to a baby, and that there are birth control options available to me to reduce the chances of becoming pregnant.
10. I understand that I may be referred at my provider's discretion to other care providers to evaluate my physical or mental condition, or to review my medication needs. Other providers I may be asked to see include but are not limited to, Psychiatrists/Behavioral Health Specialists, Endocrinologists, or Cardiologists.
11. My provider may discontinue or adjust my medications as needed.

I understand that I am responsible for meeting the terms of this Agreement and if I fail to do so my provider may refuse to prescribe controlled substances as part of my treatment. In certain instances, I may be dismissed from ETSU Health if I fail to meet the terms of this Agreement. Grounds for dismissal from ETSU Health include, but are not limited to: evidence of recreational drug use; drug diversion (selling or giving drugs to other people); altering prescriptions; obtaining controlled substances from other providers without notifying ETSU Health; abusive language toward staff; engagement in criminal activities, etc.

Continued use of controlled medications is based on my provider's judgment and a determination of whether the benefits outweigh the risks of using them. My provider may discontinue these medications at their discretion. My provider may require more frequent visits. I understand when controlled medications are used properly, they can help restore comfort, function, and quality of life. However, controlled medications may have serious side effects. I understand it is important for me to work with my provider and communicate openly and honestly with them about my medical conditions and the medications used to manage them.

By signing below, I confirm that I have read and understand this Agreement, and that I had the opportunity to have this Agreement explained to me. I confirm that I have had the opportunity to ask questions and that all my questions have been answered. By signing below, I confirm I will follow the terms in this Agreement and agree to move forward with the treatment plan as discussed with my provider.

You should NOT sign this form if you do not believe you have enough information to make an informed decision about your use of controlled medications and how they fit in to your pain management treatment plan.

Patient/LAR Signature:	_____	Date:	_____
Provider Signature:	_____	Date:	_____
Witness Signature:	_____	Date:	_____

If signed by someone other than the Patient, state your relationship to the Patient and a description of your authority to act on the Patient's behalf:

_____.