TRT Consent Form

Informed consent for testosterone replacement therapy (men)

FOR THE PRACTICE — DO NOT GIVE THIS PAGE TO PATIENTS

Review this form with your medical director and legal counsel before use. Consent requirements vary by state, and this template is not legal advice. Each risk line cites the product label section and revision date it comes from. The practice records the date it last checked the label.

HOW THIS FORM IS BUILT

- Copy the form onto your practice letterhead and have your medical director and counsel approve the wording. Blank lines are filled in by the practice or the patient. Lines ending in Initials are initialed by the patient, one at a time.
- Section 2 states both age-related facts with dates. Current labeling still says safety and efficacy in men with age-related hypogonadism have not been established (AndroGel 1.62% and Xyosted, revised July 2025; Depo-Testosterone, revised October 2025). FDA requested removal of that limitation in June 2026. A request is not an approval, and the labels checked November 16, 2026 still carry the limitation.
- FDA's February 28, 2025 class-wide labeling change added the TRAVERSE trial results to all testosterone products. It removed boxed warning language on adverse cardiovascular outcomes and added blood pressure warnings. A form that still quotes a cardiovascular boxed warning predates that change. Xyosted's July 2025 label lists its blood pressure boxed warning as removed, Depo-Testosterone carries no boxed warning, and testosterone gels keep one, for secondary exposure.
- No label sets a numeric hematocrit cutoff. The section 5 hematocrit, PSA and fertility lines get their own initials because each carries a monitoring consequence. The wording tracks AndroGel 1.62% (sections 5.2, 5.4, 5.8 and 8.3) and Xyosted (sections 5.1, 5.7 and 8.3).
- The section 4 Endocrine Society cautions come from its testosterone therapy guideline, published March 19, 2018. Keep them visibly separate from the FDA lines. The labels contraindicate testosterone in pregnant women, so the gel line asks about pregnant contacts. A prostate medication list helps staff record BPH and prostate drugs by class.
- The prescriber fills in the section 6 due dates on the day of consent, counting from the start date in section 1. Where a label says only "periodically", the form says so and the prescriber sets the date.
- Testosterone is item (84) under anabolic steroids in 21 CFR 1308.13(f). The section 7 telehealth line applies only to audio-video visits. The DEA and HHS fourth temporary extension lets practitioners prescribe Schedule II to V medicines by audio-video telemedicine without a prior in-person evaluation, from January 1 through December 31, 2026.
- Swap the section 3 source column to the label of the product you prescribe, and keep its revision date on the form. Depo-Testosterone's label covers blood pressure, hemoglobin, hematocrit and cholesterol in its own words.
- **Print from page 2 onward for patients.**

SECTIONS

1. Patient, prescriber and treatment details
2. Diagnosis and FDA approval status
3. Risks from the FDA prescribing information
4. Contraindication screen
5. Hematocrit, PSA and fertility acknowledgments
6. The signed monitoring schedule
7. Controlled substance and telehealth statement
8. Patient responsibilities, withdrawal and the decline option
9. Signatures

SOURCES FOR THIS TEMPLATE (CHECKED NOVEMBER 16, 2026)

1. AndroGel 1.62% prescribing information, revised 07/2025
   https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/022309s022lbl.pdf
2. Xyosted prescribing information, revised 07/2025
   https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/209863s020lbl.pdf
3. Depo-Testosterone label, revised October 2025
   https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=cfbb53d4-b868-4a28-8436-f9112eb01c39
4. FDA Testosterone Information page, current as of 06/23/2026
   https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/testosterone-information
5. FDA class-wide labeling changes, 02/28/2025
   https://www.fda.gov/drugs/drug-alerts-and-statements/fda-issues-class-wide-labeling-changes-testosterone-products
6. 21 CFR 1308.13(f), Schedule III, item (84) testosterone
   https://www.ecfr.gov/current/title-21/chapter-II/part-1308/section-1308.13
7. DEA/HHS Fourth Temporary Extension of telemedicine flexibilities, published 12/31/2025
   https://www.federalregister.gov/documents/2025/12/31/2025-24123/fourth-temporary-extension-of-covid-19-telemedicine-flexibilities-for-prescription-of-controlled
8. Endocrine Society, Testosterone Therapy in Men with Hypogonadism, March 19, 2018 (guideline, not FDA)
   https://www.endocrine.org/clinical-practice-guidelines/testosterone-therapy

TRT Consent Form

Informed consent for testosterone replacement therapy (men)

Practice name: _____ Form version: _____

1 Patient, prescriber and treatment details

Patient full legal name: _____

Date of birth: ____ / ____ / _____ Medical record number (MRN): _____

Phone: _____ Email: _____

Prescriber name and credential: _____

Product prescribed (name and strength): _____

Route: ☐ Intramuscular injection ☐ Subcutaneous autoinjector ☐ Gel ☐ Other: _____

Dose: _____ Frequency: _____ Planned start date: ____ / ____ / _____

2 Diagnosis and FDA approval status

AndroGel 1.62% and Xyosted labels, revised 07/2025

The form ties treatment to the product's labeled indication, primary or hypogonadotropic hypogonadism in adult males. Low morning testosterone must be confirmed on at least two separate days before starting.

Diagnosis: ☐ Primary hypogonadism ☐ Hypogonadotropic hypogonadism

Morning total testosterone, test 1: _____ ng/dL Date: ____ / ____ / _____

Morning total testosterone, test 2: _____ ng/dL Date: ____ / ____ / _____

Laboratory reference range: _____

My prescriber has explained that testosterone is prescribed for the diagnosis checked above. Initials: _____

Current labeling for this product states that safety and efficacy in age-related hypogonadism have not been established. FDA requested a change to that wording in June 2026. Initials: _____

Label status last checked by the practice on: ____ / ____ / _____

3 Risks from the FDA prescribing information

FDA prescribing information, revised 07/2025

The risks section lists every warning from the product's FDA label, cites its revision date and asks the patient to initial each line.

Patient statement: My prescriber explained each risk below, and I initial each line to confirm it.

Risk	What the label says	Source (revision)	Initials
Raised hematocrit (polycythemia)	Testosterone can raise hematocrit, which may require lowering the dose or stopping treatment. No label sets a numeric cutoff.	AndroGel 1.62% §5.2; Xyosted §5.1 (07/2025)	
Blood pressure increase	Mean blood pressure rose 1.9/1.3 mm Hg on AndroGel 1.62% and 3.9/1.5 mm Hg on Xyosted. Use is not recommended with uncontrolled hypertension.	AndroGel 1.62% §5.5; Xyosted §5.4 (07/2025)	
Prostate	Benign prostatic hyperplasia (BPH) may worsen, and prostate cancer risk may increase. The prostate is evaluated before and during treatment.	AndroGel 1.62% §5.4 (07/2025)	
Blood clots (VTE)	In the TRAVERSE trial, VTE occurred in 1.7% of men on AndroGel 1.62% and 1.2% on placebo. Treatment stops if a clot is suspected.	AndroGel 1.62% §5.3 (07/2025)	
Heart attack and stroke	In TRAVERSE, major adverse cardiovascular events occurred in 7.0% of men on AndroGel 1.62% and 7.3% on placebo.	AndroGel 1.62% §5.5, §6.1 (07/2025)	
Sleep apnea	Testosterone may make sleep apnea worse, especially with obesity or chronic lung disease.	AndroGel 1.62% §5.12 (07/2025)	
Edema	Fluid retention, with or without heart failure, may be serious in men with existing heart, kidney or liver disease.	AndroGel 1.62% §5.10 (07/2025)	
Gynecomastia	Breast tissue enlargement may develop and persist.	AndroGel 1.62% §5.11 (07/2025)	
Lipid changes	Cholesterol changes may require a dose change or stopping treatment.	AndroGel 1.62% §5.13 (07/2025)	
Liver effects	Serious liver effects are linked to high-dose oral androgens, and AndroGel 1.62% is not known to cause them. Liver tests are checked periodically.	AndroGel 1.62% §5.9 and Highlights (07/2025)	
Abuse and dependence	Testosterone has been abused at high doses, often with other anabolic steroids, with serious heart and psychiatric effects.	AndroGel 1.62% §5.6 (07/2025)	
Reduced fertility	Sperm production may be suppressed, and the impact on fertility may be irreversible. Section 5 covers this in full.	AndroGel 1.62% §5.8, §8.3 (07/2025)	
Secondary exposure (gel only)	The gel carries this as a boxed warning. Children exposed to gel have developed virilization, so children and women avoid unwashed or unclothed application sites.	AndroGel 1.62% boxed warning (07/2025)	
Depression and suicidal thoughts (Xyosted only)	Depression and suicidal ideation and behavior, including completed suicide, occurred in Xyosted clinical trials.	Xyosted §5.15 (07/2025)	

4 Contraindication screen

FDA labels; Endocrine Society 2018 guideline

The screen asks yes or no questions drawn from the FDA labels first. A yes on an FDA line is a labeled contraindication for that product.

FDA label contraindications

Breast cancer:	☐ Yes ☐ No
Known or suspected prostate cancer:	☐ Yes ☐ No
Gel only. A pregnant partner or household member who could touch an application site:	☐ Yes ☐ No
Allergy to the product or its ingredients, including sesame oil for Xyosted:	☐ Yes ☐ No
Serious heart, liver or kidney disease (Depo-Testosterone label):	☐ Yes ☐ No

Endocrine Society 2018 cautions (guideline, not FDA)

Plans to father a child in the near term:	☐ Yes ☐ No
PSA above 4 ng/mL, or above 3 ng/mL with a high risk of prostate cancer:	☐ Yes ☐ No
Elevated hematocrit:	☐ Yes ☐ No
Untreated severe obstructive sleep apnea:	☐ Yes ☐ No
Heart attack or stroke within the last 6 months:	☐ Yes ☐ No

Current prostate or BPH medicines: _____

Prescriber review of any yes answer: _____ Prescriber initials: ☐

5 Hematocrit, PSA and fertility acknowledgments

AndroGel 1.62% §5.2, 5.4, 5.8, 8.3; Xyosted §5.1, 5.7, 8.3

The patient initials three acknowledgments, covering a rising hematocrit, prostate checks before and during treatment, and fertility effects that may be irreversible.

I understand testosterone can raise my hematocrit, the share of my blood made up of red blood cells. If it becomes elevated, my prescriber may stop treatment until it falls, and some product labels require a permanent stop after a second rise. Initials: ☐

I understand my prescriber will evaluate me for prostate cancer before and during treatment, including PSA blood tests. Initials: ☐

I understand testosterone can suppress sperm production and may lead to azoospermia, meaning no sperm in the semen. Reduced fertility has been seen in some men, and the impact may be irreversible. Initials: ☐

Sperm banking was discussed with me before treatment. Initials: ☐

☐ I plan to bank sperm ☐ I declined ☐ Not applicable.

I had the chance to ask questions about these three risks, and my questions were answered. Initials: ☐

6 The signed monitoring schedule

Prescriber fills in due dates on the day of consent

The signed monitoring schedule lists each check with its sourced interval, a due date and a done date, and the patient signs it.

Check	Interval and source	Date due	Date done
Hematocrit, baseline	Before starting (AndroGel 1.62% §5.2; Xyosted §5.1)		
Morning total testosterone	Two separate days before starting (AndroGel 1.62% §2; Xyosted §2.1)		
Prostate evaluation, baseline	Before starting (AndroGel 1.62% §5.4; Xyosted §5.3)		
Hematocrit, first recheck	3 to 6 months after starting (AndroGel 1.62% §5.2), or about every 3 months on Xyosted (§5.1)		
Trough testosterone (Xyosted)	6 weeks after starting, 6 weeks after a dose change, then periodically (Xyosted §2.2)		
Prostate cancer risk and PSA	3 to 12 months after starting (Endocrine Society 2018, not FDA)		
Blood pressure	Periodically (AndroGel 1.62% §5.5; Xyosted §5.4)		
PSA, lipids, liver tests, hemoglobin	Periodically (AndroGel 1.62% Highlights)		
Hematocrit, annual	Every year after the first recheck (AndroGel 1.62% §5.2)		
Follow-up visit	Set by the prescriber		

I agree to attend the lab draws and visits listed above. Initials: ____

I understand my prescriber may pause, change or stop treatment if a result calls for it under the product labeling. Initials: ____

Practice policy on a missed check: _____

Patient signature: _____ Date: ____ / ____ / _____ Prescriber initials: ____

7 Controlled substance and telehealth statement

21 CFR 1308.13(f), Schedule III

Testosterone is a Schedule III controlled substance under federal law, so the patient agrees to use it only as prescribed and never share it.

I understand testosterone is a Schedule III controlled substance. I will use it only as prescribed and will not share, sell or give it to anyone. Initials: ____

I will tell my prescriber about any other testosterone or anabolic steroid product I use. Initials: ____

Complete only if a prescribing visit is by telehealth.

☐ My visit was an audio-video telehealth visit. I understand that federal telemedicine rules for controlled substances can change, and my practice may require an in-person visit. Initials: ____

Telemedicine rule status last checked by the practice on: ____ / ____ / _____

8 Patient responsibilities, withdrawal and the decline option

I agree to:

- Take testosterone only as prescribed, at the dose and frequency in section 1.
- Attend every lab draw and visit on the signed monitoring schedule.
- Report new symptoms promptly, including leg pain or swelling, sudden shortness of breath, urinary changes or mood changes.
- Tell my prescriber about all other medicines, supplements, herbal products, alcohol and recreational drugs I use.

I understand that:

- I may stop treatment at any time, for any reason, and I will tell my prescriber when I do.
- My prescriber may lower my dose or stop prescribing for safety reasons and will explain why.
- Alternatives include no treatment, or a different product or route, such as an injection, gel, patch or pellet.

Decision (check one):

☐ I choose to begin testosterone replacement therapy.

☐ I do not want to begin testosterone replacement therapy.

9 Signatures

I have read this form, or had it read to me. My questions were answered, and I make the decision checked in section 8.

Patient signature: _____ Printed name: _____

Date: ____ / ____ / _____

Prescriber signature: _____ Printed name and credential: _____

Date: ____ / ____ / _____

Witness or interpreter, if your state or practice policy requires it: _____

Language: _____ Date: ____ / ____ / _____

Form version: _____ Label status checked on: ____ / ____ / _____