

# ADVANCED SKIN RENEWAL

26202 Detroit Rd, Suite 100D · Westlake, Ohio 44145 · (216) 509-6345

## Consent for Peptide Therapy

This form explains peptide therapy, why your provider is recommending it, and the risks. Please read it, ask questions about anything that's unclear, and put your initials where indicated to confirm you understood.

### 1. About You

Your name: _____	Date of birth: _____
Today's date: _____	Chart number: _____

### 2. Who Is Treating You

Your provider is **Genevieve George, PA-C**, a Physician Assistant licensed in Ohio. She works under the supervision of **Dr. Dominic Haynesworth**, Medical Director of Advanced Skin Renewal. You may ask to speak with Dr. Haynesworth at any time.

- Your first visit and prescription happen in person.
- You must come in for a follow-up at least once every three months while on therapy.
- Missed follow-ups may end your therapy.

*I read Section 2. Initials: \_\_\_\_\_*

### 3. What Peptide Therapy Is

Peptides are short chains of amino acids — the building blocks of proteins. Some are FDA-approved; others aren't, but can be legally prescribed when a licensed pharmacy compounds them for you specifically. We give peptides as **subcutaneous injections** (small shots under the skin). Most patients learn to inject themselves at home after we train them.

### 4. Important Things to Know About Your Medication

**Read this section carefully.** Your medications may fall into one or more categories below. Initial each one that applies.

#### 4a. FDA-approved drugs used "off-label"

Drugs like semaglutide and tirzepatide are FDA-approved, but we may prescribe them for a use, dose, or patient the FDA hasn't specifically approved. Off-label prescribing is legal and common, but:

- The FDA hasn't reviewed this specific use.
- Long-term data for this use may be limited.
- Insurance probably won't cover it.

*I understand off-label use, if it applies. Initials: \_\_\_\_\_*

#### 4b. Compounded medications from a 503A pharmacy

Some or all of your peptides come from a state-licensed **503A compounding pharmacy** (currently [**Name of Compounding Pharmacy**]). Compounded medications differ from FDA-approved drugs in important ways:

- **Not FDA-approved.** The FDA doesn't check them for safety, effectiveness, or quality before they're dispensed.
- **Not made in FDA-regulated factories.** They're prepared by pharmacists for individual patients.
- **Quality depends on the pharmacy.** Strength, purity, and sterility depend on the pharmacy's practices. Ours is licensed and inspected, but compounded drugs still carry added risk.
- **Compounded versions aren't the same as the brand.** Compounded semaglutide isn't identical to Ozempic or Wegovy and may behave differently.

I understand my medication is compounded. **Initials:** \_\_\_\_\_

#### 4c. Peptides the FDA has flagged for safety concerns

In 2023 the FDA placed several common peptides — including *BPC-157*, *CJC-1295*, *ipamorelin*, and *thymosin beta-4* — in a category meaning the agency identified **safety concerns** or insufficient data. If your treatment includes any of these:

- The FDA has identified safety concerns or said human data are inadequate.
- There aren't large, well-controlled human trials of long-term safety or effectiveness.
- Risks may exist that aren't yet known.
- You're choosing this peptide knowing more conservative, FDA-approved options may exist.

I understand and accept these added risks. **Initials:** \_\_\_\_\_

#### 5. Your Goals — and No Promises

Your goals may include weight loss or metabolic support; skin or aesthetic improvement; recovery and healing; hormone optimization; sexual wellness; immune or general wellness; or other: \_\_\_\_\_.

**No promises about results.** People respond differently. Advanced Skin Renewal, your provider, and the Medical Director can't guarantee any particular outcome.

#### 6. Possible Side Effects and Risks

Every medication and every injection carries risk. The lists below cover the main risks but aren't complete — some are rare, some are serious, and some may not be known yet.

##### 6a. Any injection under the skin

- Pain, bruising, redness, swelling, itching, or bleeding at the injection site
- Skin reaction or infection (rarely, an abscess)
- Lumps or fat changes where you inject
- Allergic reaction — rarely, anaphylaxis
- Needle-stick injury, especially with self-injection
- Lightheadedness or fainting at injection

##### 6b. GLP-1 medications (semaglutide, tirzepatide)

- Nausea, vomiting, diarrhea, constipation, stomach pain, heartburn, burping
- Loss of appetite — sometimes causing poor nutrition or dehydration
- Pancreatitis (may need hospital care)
- Gallstones or gallbladder disease (may need surgery)
- Kidney injury, often from dehydration
- Low blood sugar, especially with insulin or sulfonylureas
- Worsening of diabetic eye disease
- Slower stomach emptying — always tell anesthesiologists you're on a GLP-1
- Hair shedding and loss of muscle/bone with rapid weight loss
- Mood changes, including depression or thoughts of self-harm (causation not proven)
- **Thyroid risk.** Animal studies showed thyroid tumors. Do not take if you or a close family member has had medullary thyroid cancer or MEN-2.
- **Pregnancy.** Don't take during pregnancy or while trying to conceive.

##### 6c. Growth hormone peptides (sermorelin, tesamorelin, ipamorelin, CJC-1295)

- Water retention, swelling, joint pain or stiffness
- Numbness or tingling (carpal-tunnel-like)
- Higher blood sugar; possible worsening of diabetes
- Headache, flushing, dizziness; effects on heart rate or blood pressure

- Theoretical risk of helping undetected cancers grow
- Long-term effects on the pituitary aren't well known

#### 6d. Healing/recovery peptides (BPC-157, TB-500/thymosin beta-4)

- Most data are from animal studies; human data are limited
- Long-term effects unknown
- Theoretical risk of helping undetected tumors grow
- Possible effects on blood pressure or blood vessels
- FDA safety concerns (see Section 4c)

#### 6e. Sexual wellness peptides (PT-141 / bremelanotide)

- Nausea (often noticeable), flushing, headache
- Short-term blood pressure increases and heart rate decreases
- Skin, gum, or facial darkening with repeated use
- Not appropriate with uncontrolled hypertension or known heart disease

#### 6f. Other peptides

For any peptide not listed above (for example, thymosin alpha-1, GHK-Cu, melanotan, epitalon, kisspeptin), your provider will discuss its specific risks with you and document the conversation in your chart. Many have limited human data; the concerns in Section 4c apply.

*I read Section 6 and asked my questions. Initials: \_\_\_\_\_*

### 7. Reasons This Might Not Be Safe for You

Tell your provider — now and any time it changes — if any of these apply:

- Pregnant, possibly pregnant, trying to conceive, or breastfeeding
- You or a close family member had medullary thyroid cancer or MEN-2
- History of pancreatitis, gallbladder disease, or severe gastroparesis
- Personal history of cancer (current, recent, or in remission)
- Diabetes (Type 1 or Type 2), insulin, or sulfonylureas
- Active eating disorder
- Severe kidney or liver disease
- Heart disease, uncontrolled high blood pressure, or recent cardiac event
- Bleeding disorder or blood thinners
- Allergy or prior bad reaction to any peptide or injectable
- Surgery or anesthesia coming up in the next 60 days
- All medications, supplements, and recreational substances you use

**Your honesty matters.** I confirm my medical history is true and complete. Withholding information could put my health at risk and may release Advanced Skin Renewal, my provider, and the Medical Director from responsibility for problems caused by anything I didn't disclose.

*I confirm my medical history. Initials: \_\_\_\_\_*

### 8. Other Choices

You can choose lifestyle changes; FDA-approved branded medications; a specialist (endocrinologist, dermatologist, dietitian, mental health provider); surgery or device options where applicable; or no treatment at all. You can switch to any of these at any time, even after starting peptide therapy.

### 9. Injecting Yourself at Home

We'll train you. After that, you're responsible for:

- Following the dosing schedule — don't change it on your own
- Storing the medication exactly as instructed (usually refrigerated, away from light)
- Inspecting before each injection — don't use if discolored, unusually cloudy, or expired
- Using a new sterile needle and syringe every time — never share
- Disposing of needles in an FDA-cleared sharps container per local rules
- Never sharing your medication with anyone
- Calling us right away with any bad reaction, infection, or unexpected symptom

## 10. When to Get Emergency Care

Call 911 or go to the ER — and let us know as soon as you can — for any of the following:

- Severe stomach pain, ongoing vomiting, or signs of pancreatitis
- Chest pain, trouble breathing, fainting, or signs of stroke
- Serious allergic reaction (face/lip/tongue/throat swelling, breathing trouble, widespread hives)
- Spreading redness, fever, pus, or severe pain at an injection site
- Severe dehydration or inability to keep fluids down
- New neck lump, ongoing hoarseness, or trouble swallowing
- Thoughts of harming yourself

## 11. Costs and Your Right to Stop

**Costs.** Peptide therapy isn't covered by insurance. Once a compounded medication is made for you, it can't be refunded — it was prepared specifically for you.

**Your right to stop.** Treatment is your choice. You can decline to start, stop at any time, or withdraw this consent in writing or in person. Stopping won't affect other care you receive at Advanced Skin Renewal.

## 12. What You're Agreeing To

By signing below, I confirm:

1. I read this form (or had it read to me) in a language I understand.
2. I had a chance to ask questions, and they were answered.
3. I understand what peptide therapy is, that some medications may be compounded or off-label, the risks and side effects, the alternatives, and the limits of what's known.
4. No one promised me a specific result.
5. I'm being treated by a PA under a Medical Director's supervision, and I'm okay with that.
6. I understand my responsibilities for follow-ups, injecting, storage, and needle disposal.
7. I am at least 18 and able to make my own medical decisions.
8. I am not pregnant, don't think I might be, and am not breastfeeding (or have discussed this with my provider and accept the added risk).
9. I am giving my consent freely.

## 13. Signatures

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*Patient signature*

*Date*

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*Patient printed name*

Complete only if someone else is signing for the patient:

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Signature of legally authorized representative

Date

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Printed name and relationship to patient

Witness to patient signature:

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Witness signature

Date

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Witness printed name

**Provider statement:** I personally discussed peptide therapy, the risks, benefits, alternatives, and the limits of what's known with this patient (or the person signing for them), and answered their questions. I believe they understand and have agreed voluntarily.

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Genevieve George, PA-C

Date

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Ohio license number

Co-signature of Medical Director, when required by protocol:

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Dominic Haynesworth, M.D., Medical Director

Date