

Informed Consent for Peptide Therapy (Use of Non-FDA Approved Peptides)

Introduction

This informed consent form is intended for patients considering **peptide therapy** at our U.S. anti-aging and wellness/functional medicine clinic. Peptide therapy involves the use of specific **lyophilized peptides** (freeze-dried amino-acid compounds) for therapeutic purposes. These peptides are produced in a Good Manufacturing Practice (GMP) facility to ensure quality and purity, and they are formulated as a lyophilized (freeze-dried) powder for stability. Because these compounds are **not classified as FDA-approved drugs or pharmaceuticals**, they cannot be prescribed or dispensed in the same manner as standard medications. This document will explain the nature of peptide therapy, its **investigational status**, potential benefits, risks, and alternatives. Please read it carefully and ask any questions before you decide whether to proceed. Your **signature** will indicate that you have been fully informed and **agree to treatment with these non-FDA approved peptides**.

What Are Peptides and Peptide Therapy?

Peptides are short chains of amino acids (essentially small proteins) that act on various biological pathways in the body. Some peptides occur naturally in the human body and help regulate hormones, immunity, healing, and other functions. In peptide therapy, we use synthetic or bioidentical versions of these peptides with the goal of supporting or enhancing certain physiological functions that decline with age or illness. The **goal and possible benefits** of peptide therapy are to attempt to **prevent, reduce, or control dysfunction associated with aging** or specific conditions by balancing hormones, reducing oxidative stress, and stimulating the body's own repair systems. For example, certain peptides may promote tissue healing, improve skin elasticity, increase muscle mass or fat loss, boost immune function, or improve energy and metabolism. These potential benefits, however, are *not guaranteed*, as individual responses can vary.

Investigational Status: It is important to understand that the peptides used in this therapy are **NOT approved by the U.S. Food and Drug Administration (FDA)** for any medical indication. In the eyes of mainstream medicine, peptide therapy is considered *new, experimental or "off-label"* treatment. "Off-label" use means using a medical product for a purpose not specifically approved by the FDA. In this case, many peptides have **no formal FDA approval at all**, which means they have **not undergone FDA review for safety, effectiveness, or quality** for treating any disease. As a result, these peptides are **investigational compounds**. They are *not* part of standard medical practice and are **not marketed as drugs or dietary supplements**.

No FDA Evaluation: Because they are not FDA-approved, these peptide products have **not been evaluated by the FDA**—they lack the extensive clinical trials that FDA-approved drugs must undergo. The FDA has cautioned that unapproved peptides obtained outside of formal clinical trials may carry risks of contamination, dosing inaccuracies, or unknown adverse effects.

You should also be aware that, since they are not approved medications, **peptides cannot be obtained through regular pharmacies with a standard prescription**. Instead, they are sourced through specialized compounding pharmacies or research suppliers. Our clinic obtains peptides manufactured under GMP conditions to maximize quality, but **no governmental agency guarantees their safety or efficacy** at this time.

Lyophilized Formulation and Quality Assurance

The peptides used in this clinic are provided in a **lyophilized (freeze-dried) powder form**, which enhances shelf stability and potency by removing moisture under vacuum. Before administration, these peptides are reconstituted using sterile diluents (such as bacteriostatic water) under aseptic conditions. You will be instructed on proper reconstitution, storage (typically refrigeration), and handling.

Manufacturing Standards and Quality Control:

The peptides used in this clinic are sourced from manufacturers that operate under strict quality control procedures. Specifically:

- The manufacturer **operates in facilities certified by the World Health Organization (WHO) for Good Manufacturing Practices (GMP) and holds ISO 9001:2015 certification**, which ensures adherence to internationally recognized standards for quality management systems.
- Each batch of peptide is subjected to **independent third-party laboratory testing for purity, identity, potency, and contaminants**.
- A **Certificate of Analysis (COA)** is available upon request for each product batch, verifying that the peptide meets defined specifications (e.g., $\geq 99\%$ purity) and confirming its analytical profile.

These quality measures are implemented to maximize **product safety, consistency, and traceability**, even though the peptides are not regulated by the FDA as approved pharmaceuticals. Despite these safeguards, it is important to acknowledge that risks still exist, particularly due to the investigational nature of these therapies.

Lyophilized Formulation: The peptides will typically be provided to you in a **lyophilized (freeze-dried) powder form** in sealed vials. Lyophilization (freeze-drying) is a process that removes water from the peptide solution under vacuum after freezing, turning it into a stable powder [fda.gov](https://www.fda.gov). This process helps preserve the peptide's potency and sterility during storage and shipping [fda.gov](https://www.fda.gov). Before use, the lyophilized peptide must be reconstituted with a sterile diluent (such as bacteriostatic water) to create an injectable or ingestible solution. **Storage and Handling:** You will be instructed on proper storage (often refrigeration) and handling of these reconstituted peptides to maintain their stability and prevent contamination.

Treatment Description and Administration

If you choose to proceed with peptide therapy, your treatment plan will be personalized to your needs and goals. The specific peptide(s) recommended, their dosage, and method of administration will be determined by your provider. **Methods of administration may include:**

- **Subcutaneous or Intramuscular Injection:** Many peptides are given as injections using a small needle either under the skin or into muscle tissue. Injections may be done in a medical office or self-administered at home after training. Aseptic (sterile) technique must be used to avoid infection.
- **Sublingual (Under the Tongue):** Some peptide formulations can be placed under the tongue as dissolving tablets or drops for absorption through the oral mucosa.
- **Transdermal:** Certain peptides might be prepared in a cream, gel, or patch applied to the skin, allowing absorption through the skin barrier.
- **Oral Capsules/Tablets:** In some cases, peptides are formulated as oral supplements. However, many peptides are not orally bioavailable (they would be digested in the stomach), so this route is limited to peptides specifically designed for oral use.

Your provider will explain which route is indicated for your therapy and provide instructions for use. **During the treatment**, regular follow-up may be required to monitor your response and adjust dosing. Because these therapies are not standard, **ongoing monitoring is important** to watch for any side effects or issues.

Potential Benefits of Peptide Therapy

Peptide therapy is offered in our clinic with the intent to improve your health or well-being in ways that conventional treatments might not. **Reported potential benefits** (which vary depending on the specific peptide used) include:

- **Anti-Aging and Regenerative Effects:** Some peptides may help counteract age-related declines. For example, certain peptides aim to increase your own growth hormone release or stimulate tissue repair, potentially improving muscle mass, reducing fat, enhancing skin elasticity, and promoting wound healing peptidesociety.org.
- **Improved Recovery and Healing:** Peptides such as BPC-157 (Body Protection Compound) have been studied for their role in reducing inflammation, decreasing pain from injuries, and speeding up healing of muscles, joints, or wounds peptidesociety.org.
- **Enhanced Immune or Metabolic Function:** Other peptides may modulate immune function or metabolism. For instance, thymosin alpha-1 is thought to support immune response, while peptide analogs of hormones can improve metabolic conditions like low growth hormone or assist in weight loss.
- **Better Sleep, Mood or Cognitive Function:** Some patients report improvements in sleep quality, mood, or mental clarity with certain peptide therapies, especially those that influence brain neurotransmitters or hormones. (For example, some peptides affect GHRH/GH levels which can indirectly improve sleep and mood.)

Please note that **these benefits are not guaranteed or proven** to the same extent as traditional FDA-approved treatments. While clinical research and anecdotal reports suggest potential advantages, results vary widely. You may experience all, some, or none of the anticipated benefits. **No promise or guarantee of specific outcomes can be made**nourishedmedspa.squarespace.com. Peptide therapy is considered **adjunctive and experimental** – it does not replace other treatments your primary care physician may recommend for your condition.

Potential Risks and Side Effects

Before starting peptide therapy, it is crucial that you understand the **possible risks and side effects**, as well as the unknowns, associated with these compounds. Because peptides are biologically active substances, they can affect various systems in the body. **Known or reported side effects** depend on the peptide used, but some examples include:

- **Injection Site Reactions:** If injected, you may experience pain, redness, bruising, bleeding, or irritation at the injection site. Proper technique can minimize these issues. Infection at the injection site is a rare but serious risk if sterility is not maintained.
- **Immune Reactions:** Your body might recognize a peptide as foreign and produce antibodies against itincrediblehealthcenter.com. In some cases, this could reduce the peptide's effectiveness over time or cause allergic reactions. Signs of an allergic reaction include rash, itching, swelling, dizziness, or difficulty breathing (seek medical help immediately for any severe reaction).
- **Systemic Side Effects:** Depending on the peptide, systemic effects can occur. For example, growth-hormone-related peptides (GHRH analogs or secretagogues like CJC-1295/Ipamorelin) may cause **fluid retention, transient blood sugar changes, or swelling**incrediblehealthcenter.com. You might notice increased hunger or tiredness. Peptides affecting metabolism or appetite (like GLP-1 analogs) can cause **nausea, vomiting, diarrhea, constipation, or headaches** in some individualsfda.gov.
- **Hormonal Effects:** Peptides that alter hormone levels could potentially lead to imbalances. For instance, those boosting growth factors or other hormones might theoretically affect cortisol, thyroid, or insulin levels. Careful dosing aims to avoid this, but it remains a risk.
- **Unknown Long-Term Risks:** There is **limited long-term data** on many research peptides. Potential risks such as effects on organ systems, cancer risk (for peptides that promote cell growth), or other unintended consequences are **not fully known**. **The FDA has noted concerns** that misuse or unmonitored use of certain peptides can lead to serious side effects like organ damage or other chronic conditionsrupahealth.com, but robust safety data is lacking. By participating, you acknowledge these uncertainties.
- **Quality and Purity Concerns:** While our sources are GMP-certified, peptides that are not FDA-approved are not subject to FDA lot-by-lot quality oversight. There is a **risk of contamination or impurities** in any compounded or research-grade product. Dosing variations can also occur. The FDA warns that unapproved peptides obtained from unofficial sources may be of **unknown quality and potency and could be harmful**spring-nutrition.org. We mitigate this by using reputable compounding pharmacies/labs and testing when possible, but **some risk remains**.

- **Specific Contraindications:** Certain peptides should **not** be used in specific populations. For example, growth-promoting peptides **should not be used if you have any known cancer** (since they might stimulate tumor growth)incrediblehealthcenter.com. Women who are pregnant, breastfeeding, or trying to conceive should avoid most experimental peptides, as effects on a developing fetus/infant are unknown. You must inform us of **all your medical conditions** so we can evaluate if a peptide is unsafe for you.

Please **immediately report** any side effects or unusual symptoms to the clinic. Many side effects are dose-dependent and resolve when the dose is adjusted or stoppedincrediblehealthcenter.com. We will work to manage any adverse reactions, but **it is possible that you may experience an unforeseen or serious reaction** requiring medical attention. In signing this consent, you acknowledge that you understand the possible risks, both known and unknownincrediblehealthcenter.comincrediblehealthcenter.com.

Alternatives to Peptide Therapy

Peptide therapy is **completely optional and voluntary**. You are **not required** to undergo this or any treatment at our clinic. Before consenting, consider the alternatives:

- **No Treatment / Do Nothing:** You may choose not to use peptide therapy and instead manage your condition or age-related changes with standard care or lifestyle adjustments. If you opt for no peptide treatment, **the likely outcome is that any current symptoms or age-related decline may continue or progress** at their natural pacenourishedmedspa.squarespace.com. (For example, reduced energy or tissue healing might remain as is, and age-related risks might increase over time.) This option carries *no direct treatment risks*, though any ongoing health issues would be addressed by other means if needed.
- **Conventional Medical Therapies:** Depending on your health goals, there may be FDA-approved medications or therapies available. For instance, if your goal is hormone balance, FDA-approved hormone replacement or other endocrine treatments might be considered. If improved healing or pain relief is the goal, physical therapy, surgery, or approved medications (like anti-inflammatories) might be options. These standard treatments have been more rigorously tested but could have their own risks and side effects which should be discussed with your primary provider.
- **Lifestyle and Alternative Approaches:** Much of functional wellness can be pursued with lifestyle changes (diet, exercise, sleep, stress reduction) and non-peptide supplements or therapies. For example, to improve muscle mass or well-being, one might adjust nutrition and exercise, use approved supplements, or try modalities like physiotherapy or acupuncture. These approaches can be used **instead of or alongside** peptide therapy.
- **Other “Off-Label” or Experimental Therapies:** You may also consider other integrative therapies offered by providers, or choose to seek care from another practitioner who uses different methodsnourishedmedspa.squarespace.com. If you desire cutting-edge treatments but are uncomfortable with peptides, you might explore clinical trials or other investigational products under medical supervision.

We have discussed the above alternatives with you, including their **risks and benefits**, as appropriate to your situation nourishedmedspa.squarespace.com. You acknowledge that you understand you **have the right to refuse** peptide therapy and pursue these alternatives without prejudice or impact on your ability to receive other care nourishedmedspa.squarespace.com.

Financial Considerations

Because peptide therapy uses non-FDA approved substances, it is generally **not covered by insurance**. You will be responsible for the cost of the peptides and any related supplies or laboratory monitoring. Payment policies (including any refund policy for unused doses) have been explained to you separately. **No refunds** can be provided for peptides/treatments already administered, regardless of outcome, as these are individualized medical products. This consent, however, is purely to document your informed decision; financial arrangements are covered in a separate agreement.

Patient Rights and Acknowledgments

Before you sign this form, please note the following rights and facts:

- **Voluntary Participation:** Your consent to peptide therapy is **completely voluntary**. You may decline or withdraw from treatment at any time, even after signing this form, without any penalty or loss of benefits to which you are otherwise entitled. Peptide therapy is considered an elective, optional treatment for wellness incrediblehealthcenter.com.
- **Right to Ask Questions:** You have the right to ask **any questions** about peptide therapy, now or during the course of your treatment. Our medical team will do its best to answer your questions with the information available. Do not sign this consent until all your questions have been answered to your satisfaction.
- **Explanation of Treatment, Risks, and Alternatives:** The nature of peptide therapy, the intended benefits, the possible risks/side effects, and the available alternatives (including no treatment) **have been explained to you** in detail by your provider nourishedmedspa.squarespace.com. You understand the explanation given.
- **No Guarantee of Results:** You understand that **no guarantee or assurance** has been made to you about the outcome of peptide therapy nourishedmedspa.squarespace.com. Medicine is not an exact science, and this is especially true for experimental therapies. You accept that the treatment may **not** achieve the results you seek.
- **Not Standard Care:** You acknowledge that this therapy is *outside* standard conventional medical practice and is being pursued at your request/interest in pursuing innovative or preventive approaches. Mainstream physicians might not endorse this treatment, and its efficacy is not conclusively proven incrediblehealthcenter.com.
- **Potential Need for Medical Care:** You understand that in the event of an adverse reaction or if your condition changes, you may need additional medical care (for example, if side effects occur, you might need lab tests or treatment to manage them). You agree to promptly inform the clinic of any concerning symptoms and to seek emergency care if a serious reaction occurs.

- **Disclosure of Health Information:** You have fully disclosed your medical history, conditions, allergies, and all medications or supplements you take to your provider. This is important for your safety. You agree to update the clinic about any changes in your health or medications during your peptide therapy course nourishedmedspa.squarespace.com.
- **Pregnancy:** If you are a female of childbearing potential, you confirm that you are not currently pregnant or nursing, and you agree to use appropriate contraception or avoid pregnancy during peptide therapy. Should you become pregnant, you will inform the provider immediately and understand the peptide treatment will be re-evaluated or stopped for safety.
- **Withdrawal of Consent:** You understand that you can withdraw your consent and stop peptide therapy at any point. If you choose to discontinue, inform your provider so we can safely taper or stop the peptides (some may require gradual dose reduction). There is no penalty for changing your mind.
- **Consent to Treatment:** By signing, you are not waiving any legal rights or releasing the clinic from liability for negligence. You are simply acknowledging that you are informed about the therapy and agree to proceed with treatment understanding the risks and potential benefits.

Consent and Authorization

Patient Declaration: I have read and fully understand the contents of this consent form. All sections (purpose, nature of treatment, investigational status, benefits, risks, alternatives, and patient rights) have been explained to me in terms I understand. I have had the opportunity to discuss this information with my healthcare provider, and all of my questions have been answered to my satisfaction. I understand that I have the right to refuse or discontinue peptide therapy at any time. By signing below, I **voluntarily consent** to receive peptide therapy using non-FDA approved peptides. I understand and accept the risks involved, and I agree to proceed under the care of the medical provider at the clinic.

I also confirm that I am **of legal age** and mentally competent to provide consent, and I am not under the influence of any substance that would impair my decision-making at the time of signing. This consent form will be kept as part of my medical record. I will be given a copy of this form upon request.

Patient Name (Print):

Patient Signature: **Date:**

Provider Statement: I, the undersigned provider, have explained the above peptide therapy to the patient, including the nature of the treatment, the lack of FDA approval, the potential benefits, risks, and alternative options. I have answered all the patient's questions. To the best of my judgment, the patient has been adequately informed and has consented to proceed with peptide therapy incrediblehealthcenter.com.

Provider Name & Title (Print):

Provider Signature: **Date:**

Witness (if required): **Signature/Date:**

Sources: The information in this consent form is informed by current knowledge and guidelines regarding peptide therapy and investigational use of non-FDA approved compounds, including FDA statements and expert resources on peptide use and safety fda.gov/spring-nutrition.org. The form content was developed with reference to sample peptide therapy consent forms from medical practices incrediblehealthcenter.com and incorporates recommendations for informed consent in experimental treatments nourishedmedspa.squarespace.com.