

INFORMED CONSENT FOR POLYPEPTIDE (PEPTIDE) TREATMENT AND RELEASE AGREEMENT

Patient Name: _____ DOB: _____ Date: _____

I hereby consent to be treated with polypeptide therapy, specifically:

RISKS:

Reactions to Peptide Therapy

As is the case with the administration of any parenteral therapy, systemic, or local allergic responses can sometimes result. I understand that if I develop an allergic reaction as a result of peptide therapy, I will seek medical attention promptly.

Initial _____

Common Reactions

The most common reaction to parenteral peptide therapy is local irritation around the injection site, which occurs in around one of every six patients. This irritation is characterized by redness, tenderness, or swelling. Though this side effect is relatively common, only a small minority of patients find the irritation bothersome enough to suspend therapy.

Initial _____

Rare Side Effects

There are other side effects which occurred in less than one percent of patients. These side effects include: drowsiness, hives, vomiting, headache, nausea, difficulty swallowing, hyperactivity, chest tightness and pallor, distortion in perception of taste and flushing of the skin. Initial _____

Lab Results

Initial Clinical Tests have shown that increased blood-serum levels of Insulin-Like Growth Factor One (IGF-1), Human Growth Hormone, Alkaline Phosphatase (ALKP) and in-organic mineral phosphorus can occur as a result of peptide therapy.

Initial _____

A significant portion of peptide therapy patients develop antibodies against Growth Hormone Factor during at least one point of therapy. There is no clear assessment of the significance of the presence of these antibodies, and the levels of these antibodies can change quickly from test to test. A positive result at one juncture regularly turns into a negative result after the next test. The production of the antibodies does not seem to have any adverse effect on the patient. Initial _____

Drug Interaction/Clinical Research

Taking glucocorticoid steroids in combination with peptide therapy may reduce the effectiveness of the therapy. There have been no clinical studies regarding formal medications interactions, fertility impairment, carcinogenicity or linking polypeptide therapy to genetic abnormalities. Initial _____

Pregnancy/Nursing

Animal research suggests that at a dosage somewhere between three and six times the normal daily dosage that a human patient receives adjusted for physical surface area, minor fetal changes occurred in rabbits and rats. There have been no adequately controlled studies regarding the usage of polypeptide therapy by women who are pregnant. Peptide therapy should NOT be administered to women that are pregnant. It is unknown if polypeptide treatment results in its secretion in human milk and possible negative effects on infant health. There are many medications that are released by the mother in the nursing process, and for this reason mothers and physicians should exercise caution when using polypeptide therapy while nursing. I agree I will not be breastfeeding during peptide therapy. I certify there is no way that I can be pregnant and/or nursing. Initial _____

Needle Disposal

If my healthcare provider approves home usage with needles, I will be provided with or directed to a location which provides SHARPS containers meant for the proper disposal of used needles and syringes accumulated as a result of polypeptide therapy. These containers are puncture resistant and are a safety measure to protect both patient and anyone who may come in contact with the used needles and syringes. I will follow the proper needle disposal instructions. In addition, I acknowledge I understand the dangers of reusing syringes and needles as well. Initial _____

Peptide Therapy Dependency and Abuse

There is no evidence to suggest that the use of peptide therapy for any period of time will result in any sort of dependency or proclivity toward abuse. The general pharmacology of peptide therapy does not produce any addictive effect, and clinical trials have produced no evidence of such an effect. Initial _____

Never Take More Than Prescribed

It is not recommended to exceed the recommended dosage of peptide therapy prescribed by your healthcare provider. Overdose will not provide better results. It will only increase the occurrence of side effects. Initial _____

Off-Label Use of FDA-Approved Drugs

I also understand that polypeptide therapy may include the off-label use of FDA-approved drugs. Off-label use means an FDA-approved drug is used in therapies and treatments for which the drug was not specifically approved. As much as forty-six percent of certain classes of prescriptions are for "Off-label" use of FDA-approved drugs. Initial _____

I understand that no guarantee has been made to me regarding the outcome of this treatment. I also understand that the benefits derived from these therapies will stop if the therapies are discontinued. In addition, I assume full liability for any adverse effect that may result from no negligent prescribing of treatments involved in the therapies and medical care prescribed or recommended by _____, and I release him/her from any and all claims (legal or otherwise), grievances, or damages (monetary or otherwise) arising from my treatment as their patient. I hereby confirm and attest that I am not under the jurisdiction of any governing body that prohibits the use of peptide therapy, such as sports, organizations, competitive athletic/bodybuilding organizations, Olympic sports teams or the like.

I certify that I am under the care of another physician or physicians for all other medical conditions. I will consult with this or these physician(s) for any other medical services I may require.

I hereby understand, agree, and confirm that the therapies and treatments recommended by _____ are elective. The risks involved, and the possibilities of complications have been explained to me. I understand that any prescribed therapies and treatments are based on medical judgment and expertise in this field of medicine. I understand that I may suspend or terminate treatment at any time, and I hereby agree to immediately notify _____ of any such suspension or termination.

I acknowledge that there are no guarantees relating to the effectiveness of peptide therapy and that I have done my own research and have made a well-informed decision to start the therapy and understand that there are no guarantees for my individual performance or my ability to adhere to the program. I also understand that there are NO REFUNDS. Initial _____

Signature _____

Date _____

Witness _____

Date _____