

Informed Consent for Thyroid Hormone Replacement Therapy

Patient Name: _____ **DOB:** _____

This form is an “Informed Consent Form” to inform you about the thyroid hormone replacement therapy that your healthcare provider(s) has/have recommended for you. You should read this form carefully and ask any questions before you decide whether or not to provide your consent for this therapy.

As with any medical treatment, there are potential benefits and risks of both consenting to treatment and foregoing treatment. Treatments have potential risks of unsuccessful results, complications, and injury from both known and unforeseen causes. There is no guarantee made as to a result or cure. You have the right to be informed of such risks as well as the nature of the treatment, the expected benefits or effects of such therapy, the available alternative methods of treatment and their risks and benefits, and the controversies regarding the most appropriate diagnosis and treatment of low or suboptimal thyroid hormone levels.

The Principles of Medical Ethics adopted by the American Medical Association in 1980 states that a physician shall continue to study, apply, and advance scientific knowledge, make relevant information available to patients, colleagues, and the public. An essential component of informed consent requires that in the absence of medical certainty, patients have the opportunity to choose among medically indicated treatments. The American Medical Association’s code of ethics states, “The principle of patient autonomy requires that competent patients have the opportunity to choose among medically indicated treatments and to refuse any unwanted treatments.” Because choice can only be preserved by understanding and acknowledging divergent viewpoints on treatment options and providing those treatment options, this document, along with the discussion by your healthcare provider, is designed to provide you with such information.

Information Regarding Thyroid Hormone Supplementation Therapy: You have been diagnosed with a relative or absolute deficiency of thyroid hormone and may potentially benefit from thyroid hormonal supplementation. Your healthcare provider has recommended treatment with oral thyroid hormone replacement therapy(ies). The goal is to provide you with the most up-to-date therapy options and to be sure you understand the reason that this therapy is being prescribed as well as the potential risks of therapy and the potential risk of not undergoing treatment. It is also important that you know there are significant controversies regarding the best method to diagnose low thyroid levels, the best methods of treatment, and the most appropriate way to monitor and decide proper dosage and therapy. This is especially true when “standard” blood tests look “normal,” or fall within “normal” reference ranges. Thus, you may consult another healthcare provider who does not agree with the therapy. This document provides extensive information that will be summarized by your

healthcare provider so that you understand the basis for diagnosis, the treatment method, and the potential risks and benefits of treatment as well as risks of not treating.

Do not undergo therapy until you have reviewed this document with your healthcare provider and thoroughly understand the potential risks and benefits of treatment, and have all of your questions answered. You will be able to keep a copy of this document to review before undergoing or continuing treatment, and agree that you will read the document in its entirety. Please schedule an appointment with your healthcare provider if you have questions or concerns regarding the controversies, risks, and benefits of treatment (and not treating) thyroid hormone deficiency or suboptimal thyroid hormone function.

The diagnosis and treatment used may be considered non-conventional, complementary, or alternative, and other healthcare providers may disagree with the need for treatment, the method of treatment, dosing or the methods of monitoring. You agree to undergo testing as recommended by your provider, and report any potential side-effects immediately.

An article “*Controversies and Treatment of Hypothyroidism*”, is available for review on our website. It outlines the controversies involving the diagnosis and treatment of low thyroid, and is designed to inform you about the controversies to insure you are able to make an informed decision whether or not to undergo treatment after knowing any potential risks that may be involved. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed so that you may give or withhold your consent to treatment.

Therapeutic Basis: Based on clinical criteria, serologic analysis, and/or metabolic/physical testing, patients may demonstrate presence of low or suboptimal thyroid hormone levels and may benefit from therapy with thyroid replacement/supplementation/optimization. Thyroid hormone replacement therapy can be used to augment thyroid hormone levels in a number of conditions where diminished levels of free T3 and/or free T4 are shown to be suboptimal. Thyroid hormone replacement therapy is shown to be beneficial for thyroid deficiency caused by relative reduction in the secretion of thyroid hormones from the thyroid gland (either due to primary thyroid disorder or from hypothalamic/pituitary dysfunction), and from low tissue or cellular levels caused by dysfunctions in the local control of thyroid activation and transport at the cellular level. Thyroid hormone works at a cellular level to stimulate diverse metabolic activities in most tissues, leading to an increase in energy and metabolic rate. Thyroid hormone is necessary for the proper functioning of other glands and organs. Cellular levels cannot be tested directly so estimates are based on serologic, clinical criteria, as well as metabolic and physical testing.

Thyroid hormones may be used alone, or in conjunction with one another, based upon the patient’s individualized needs. After review of your serologic analysis, clinical history, metabolic and physical testing, presentation and reported symptoms, your healthcare provider is

recommending thyroid hormone replacement. This can be T4 or T3 given separately, in a desiccated thyroid preparation, or a combination of multiple types.

Objectives: The goal of thyroid hormone replacement therapy is to optimize hormone levels and to reduce symptoms associated with low cellular levels of these hormones.

Potential Risks Associated with Treatment: Adverse side effects of any thyroid hormone replacement can include rapid heartbeat, irregular heartbeat, chest pain or tightness, shortness of breath, nervousness, irritability, sleeplessness, tremors, excessive sweating, heat intolerance, weight loss, hair loss, or changes in menstrual periods. Like exercise which is healthy but can trigger a heart attack or death in someone with underlying heart disease, thyroid replacement therapy is also usually heart healthy but could unmask an abnormal heart rhythm and precipitate a heart attack which could cause damage to the heart muscle or even death. If you have a history of heart palpitations or have been diagnosed with a heart condition, notify your healthcare provider before beginning or increasing the dose of any thyroid replacement therapy. Stop taking your thyroid hormone replacement and seek medical evaluation immediately if any symptoms of chest pain, rapid or irregular heart beat occur. If you are currently taking any thyroid hormone prescribed by another healthcare provider, discuss this medication with your Nova Wellness Center provider prior to initiating any additional thyroid hormone replacement. Studies show that thyroid hormone replacement is not likely to cause osteoporosis when appropriately monitored, but **if the thyroid dose is too high for an extended period of time, it could worsen bone loss/osteoporosis.** Laboratory testing can be done to monitor the amount of bone breakdown, as well as undergoing periodic DEXA scans to monitor bone mineral density.

Optimal thyroid levels during pregnancy are essential. Although there is no conclusive data showing that T3 only replacement is harmful during pregnancy, there is also little data on the safety of using T3 replacement alone during pregnancy. Notify your healthcare provider if you are pregnant, or if you are planning to become pregnant during this therapy.

Potential Risks of NOT Treating: Low levels of thyroid can cause, contribute to or be associated with fatigue, depression, heart disease, high cholesterol, chronic fatigue syndrome, fibromyalgia, weight gain, irritable bowel syndrome, cold intolerance, body aches, thinning hair or hair loss, dry skin, heavy periods, premenstrual syndrome, cold extremities, water retention, constipation, muscle cramps, stiff or painful joints, hoarse voice, poor immunity, and diminished sweating.

As with other therapies, the response to thyroid hormone replacement/supplementation can vary significantly, you agree to discuss any change in your therapy with your prescribing healthcare provider.

<i>Potential Benefits</i>	<i>Potential Risks</i>
<ul style="list-style-type: none"> ● Protects against heart disease ● Increases metabolism ● Increases weight-loss ● Increases concentration and memory ● Increases energy, mood, and motivation ● Prevents hair loss and dry skin ● Improves depression ● Improves chronic fatigue syndrome and fibromyalgia ● Improves cholesterol levels ● Improved PMS and menstrual irregularities 	<ul style="list-style-type: none"> ● Increases flushing of the face ● Rapid or irregular heartbeat ● Changes menstrual cycle ● Sensitivity or intolerance to heat ● Nervousness ● Seizure ● Stomach cramping and diarrhea ● Irritability or rapid changes in mood ● Osteoporosis ● Difficulty falling asleep or staying awake ● Chest pain ● Shortness of breath ● Weight loss ● Anxiety

You agree that you have been given an opportunity to ask questions about your condition, about conventional “standard” methods of diagnosis and treatment, about integrative, alternative and complementary forms of diagnosis and treatment, about the risks of treatment and the risks of non-treatment, and the risks and hazards involved, and believe that you have sufficient information to give informed consent.

You certify that this form has been fully explained to you, that you have read it or have had it read to or explained to you, and that you understand its contents. You agree not to undergo any treatments unless you fully understand the treatment and have discussed possible risks and benefits.

Patient Signature

Date

Statement of Healthcare Provider:

I have explained the risks and benefits of the therapy as detailed above. The patient has verbalized his/her understanding of those risks and benefits, and gives verbal consent to initiate/continue this therapy. I have explained the therapy, its intended benefits and risks, and possible reactions to the patient. I have confirmed that the patient has no further questions and wishes to initiate/continue thyroid hormone replacement therapy.

Healthcare Provider Signature

Date