

Informed Consent For Thyroid Hormone Supplementation Therapy

(Name of patient)

1. Your physician(s) is Dr. Rashel Tahzib DO.
2. This form is called an "Informed Consent Form." Its purpose is to inform you about the thyroid hormone replacement therapy that your physician has recommended for you. You should read this form carefully and ask any questions before you decide whether or not to give your consent for this therapy.
3. As with all treatments, there are potential risks and benefits of both treatment and from forgoing treatment. Treatment carries the potential risk of unsuccessful results, complications and injury from both known and unforeseen causes. There is no warranty or 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.
4. 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 by providing those treatment options, this document, along with the discussion with your physician, is designed to provide you with such information.

Background: You have been diagnosed with a relative or absolute deficiency of thyroid hormone and may potentially benefit from thyroid hormonal supplementation. Your doctor 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 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. We also feel it is important that you know there are significant controversies regarding the best method to diagnosis 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". Thus, you may consult another doctor who does not agree with the therapy. This document provides extensive information that

will be summarized by your physician so that you understand the basis for the 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 physician and thoroughly understand the potential risks and benefits of treatment and have all your questions answered. You are able to download this document to re-review before undergoing or continuing treatment and agree that you will read the document in its entirety before your next appointment or refill and call or come into the office to answer any questions about the controversies, risks and benefits of treatment (and not treating) before continuing treatment.

The diagnosis and treatment used may be considered non-conventional, complementary or alternative and other physicians 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 physician and report any potential side-effects immediately. The article entitled Controversies in the Diagnosis and treatment of Hypothyroidism, which is attached to this consent, outlines the controversies involving in the diagnosis and treatment of low thyroid and is designed to inform you about the controversies and to insure that you are able to make an informed decision whether or not to undergo treatment after knowing the risks and hazards 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 the procedure with treatment.

Therapeutic Basis: Based on clinical criteria, serologic analysis and/or metabolic/physical testing, patients may demonstrate the 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 T4 are shown to be suboptimal. Thyroid hormone replacement therapy is shown to be beneficial for a thyroid deficiency caused by a relative reduction in the secretion of thyroid hormones from the thyroid gland (either due to primary thyroid illness 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 basal 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 (systems) 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 physician is recommending thyroid replacement. This can be T4, T3 or a combination of the two.

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:** 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 is also usually heart healthy but can unmask a heart attack or abnormal rhythm (and even cause death or heart muscle weakness). If you have a history of heart palpitations or have ever been diagnosed with a heart/cardiac condition, notify your physician before beginning or increasing the dose of any thyroid replacement therapy, and stop taking your thyroid replacement if any symptoms occur and call your physician. If you are currently taking any thyroid hormone prescribed by another physician, discuss this medication with Dr. Rashel Tahzib prior to initiating any additional thyroid 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. Serum 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 straight T3 is harmful during pregnancy, there is also little data on the safety of straight T3 during pregnancy. Notify your physician if you are pregnant, suspect that you have become 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.

Potential Benefits

- 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

Potential Risks

- 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

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 physician.

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 this 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 and further agree to read Controversies in the Diagnosis and Treatment of Hypothyroidism before the next appointment or next refill, whichever is sooner, and contact us if needed to ask any questions about the controversies, risks and benefits of treatment (and not treating) and not continue treatment until all your questions are answered.

Signature of Patient

Date