

### **PATIENT CONSENT FOR THYROID TREATMENT**

This form is called an "Informed Consent Form." Its purpose is to inform you about the thyroid hormone replacement therapy that your medical provider(s) has/have 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.

1. 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.

2. 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 with your medical provider, is designed to provide you with such information.

### **BACKGROUND**

You have been diagnosed with a relative/sub-optimal or absolute deficiency of thyroid hormone and may potentially benefit from thyroid hormonal supplementation. Your medical 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 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 medical differences of opinion or 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 are “normal”, meaning that the result is within the normal laboratory reference range for the test. The diagnosis and treatment used may be considered non-conventional, complementary or alternative and other physicians may disagree with the need for treatment at all, the method of treatment, dosing or the methods of monitoring. Thus, you may consult another doctor who does not agree with our diagnosis or therapy.

This document provides extensive information that will be summarized by your medical provider and staff, so 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 medical provider and thoroughly understand the potential risks and benefits of treatment and have all your questions answered. 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 for this therapy.

#### **THERAPEUTIC BASIS**

Based on clinical criteria, serologic (lab) analysis and/or metabolic/physical exam, patients may demonstrate the presence of low or suboptimal thyroid hormone levels [at the lower end of the normal laboratory reference range] 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 has been 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 (labs), clinical criteria (symptoms) as well as metabolic and physical exam findings.

I understand that providers at DeRosa Medical and MiraVita base their treatment of thyroid disorders on their own extensive research and interpretation of the data and medical literature, as well as clinical experience and patients' response to therapy, and may not conform to diagnostic and/or treatment guidelines issues by some medical organizations. In this regard, they do not rely solely on the traditional TSH/T4 testing (as many other providers do) for diagnosing and treating thyroid disorders or monitoring treatment.

\_\_\_\_\_ **Patient Initials**

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 provider 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 OF TREATING WITH THYROID REPLACEMENT**

Adverse side effects of any thyroid hormone replacement therapy 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, seizures, stomach cramping and diarrhea, 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 trigger a heart attack or abnormal heart rhythm (and even cause death or heart muscle damage). 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.

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 if deemed clinically necessary.

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.

If you are currently taking any thyroid hormone prescribed by another physician, discuss this medication with your DeRosa Medical/MiraVita provider prior to initiating any additional thyroid replacement.

#### **POTENTIAL RISKS OF NOT TREATING WITH THYROID REPLACEMENT**

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.

#### **PATIENT FOLLOW UP AND RESPONSIBILITY**

As with other therapies, the response to thyroid hormone replacement/supplementation can vary significantly, you agree to discuss any change in your condition or therapy with your prescribing medical provider. You agree to notify your provider if any new onset side effects after starting your thyroid replacement such as 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. You agree to undergo testing as recommended by your medical providers and report any potential side-effects immediately.

\_\_\_\_\_ Patient Initials

---

**SUMMARY**

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 this agreement. You agree to call come into the office 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 or clarified.

You are able to download this document to re-review before starting or continuing treatment and agree that you will read the document in its entirety before your next visit 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. You also agree not to start any medications until you are comfortable with this agreement and willingness to sign this document.

**PATIENT SIGNATURE and DATE**

\_\_\_\_\_

**STATEMENT OF CLINICAL EDUCATOR**

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 thyroid replacement/optimization therapy. I have explained the risks and benefits of the therapy as detailed above. The patient has verbalized to me his/her understanding of those risks and benefits giving verbal consent to initiate this therapy.

**NAME OF PROVIDER/EDUCATOR EXPLAINING PROCEDURES/THERAPIES**

\_\_\_\_\_ Date: \_\_\_\_\_

**INSTRUCTIONS ON HOW TO PROPERLY TAKE YOUR THYROID MEDICATION**

At DeRosa Medical/Miravita, we DO NOT recommend taking generics of thyroid therapies. We will be monitoring your levels closely and attempting to find the “perfect” therapeutic levels that work best for your body. Generic thyroid preparations do not provide for even consistent levels of hormones and can be switched month to month due to pharmacy and manufacturing changes. This could result in month to month serum changes which make it harder to keep your levels consistent but also increase the risk of this medications not working, but more importantly increasing your risk for side effects. Please discuss with your provider if your pharmacy costs are prohibitive.

You have been prescribed the following thyroid therapies.

- \_\_\_\_\_ **Armour**
- \_\_\_\_\_ **Naturthroid**
- \_\_\_\_\_ **Cytomel (liothyronine)**
- \_\_\_\_\_ **Synthroid**
- \_\_\_\_\_ **Levoxyl**
- \_\_\_\_\_ **Other** \_\_\_\_\_

**YOUR DOSE AND SCHEDULE OF YOUR MEDICATION IS AS FOLLOWS**

\_\_\_\_\_mg

**Please take your thyroid** \_\_\_\_\_

Take thyroid hormone medication with a full 8 oz. of water and on an empty stomach to allow for maximum absorption. This means waiting 30 minutes to 1 hour after taking your medication to eat, or waiting 2 to 3 hours after eating to take your medication. You may drink coffee with your medication.

Take your medication at the same time every day. If you miss a dose, DO NOT double up on your medicine by taking 2 doses the next day. Most doctors recommend putting your medicine in a convenient place where you’ll remember to take it first thing in the morning.



## THYROID TREATMENT PATIENT INSTRUCTIONS -2-

Take vitamins or supplements with iron at least 2 to 3 hours apart from thyroid hormone. Iron and vitamins can interfere with thyroid hormone absorption if taken too close together. Be careful about taking calcium and calcium-fortified orange juice at the same time as thyroid hormone. Also, don't take antacids within 2 hours of taking thyroid hormone.

Many medications such as H2 blockers, PPI's, cholesterol medications should not be taken with your thyroid dose. Please discuss your medication regimen with your provider to ensure that you are taking your other meds at a time that does not interfere with absorption.

**PLEASE NOTIFY YOUR PROVIDER IF ANY SIDE EFFECTS OCCUR**