

## **INFORMED CONSENT**

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**Protocol ID “TiroNod”**

**ID number NCT03535974, titled:**

**“Efficacy of a Spirulina Supplement for Amelioration of benign thYroid nodules (ESSAY)”**

**INFORMED CONSENT**  
**(translation from Romanian)**

**Clinical Study "Spirulina-based combination for benign thyroid nodules"**

PI Prof Dr Corin Badiu, Co-PI Dr Felician Stancioiu

Date \_\_\_\_ / \_\_\_\_ / \_\_\_\_ Name \_\_\_\_\_

Date of birth / CNP / \_\_\_\_\_ Diagnosis \_\_\_\_\_

I (family name, first name) \_\_\_\_\_ declare that I agree to participate in the clinical trial "Spirulina-based combination for benign thyroid nodules"

I understand that in this study I will have to consume for 3 months (12 weeks) either a dietary supplement containing spirulina, boswellia and curcumin, or a placebo (substance without direct physiological effects on the body). This type of supplement has been administered so far in patients with thyroid nodules and a significant decrease in the size of these nodules has been observed after several weeks of treatment. To date, there is no known treatment that will reduce the size of thyroid nodules. This study will help to understand the benefit and to establish the limits of the effect on this thyroid nodule of this type of supplement.

Specifically, I will have to take for 3 months, 2 times a day (in the morning and at lunch, about 30 minutes before meals), 2 capsules each from either the supplement tested which contains the active ingredients with spirulina, or placebo. It will also be necessary that three times during this study (initially at first visit, after 6 weeks – second visit- and after 12 weeks – third and last study visit).

I acknowledge that I was previously evaluated on the condition of the thyroid and thyroid nodules by performing a thyroid ultrasound and blood tests.

If I choose to participate fully in the study, (ie to take the capsules 12 weeks and to do the 3 ultrasound and blood tests at the three study visits during 12 weeks) For these analyzes, as well as for the supplement administered, I will not have to pay.

If I choose not to complete the study in the absence of objective reasons (illness, accident, etc.), I accept to pay the value of the tests and treatments performed as follows: thyroid ultrasound with nodule measurement and printout -100 lei, blood tests (TSH, fT3, fT4, serum copper) - 160 lei, supplement 20 lei / bottle (placebo is free of charge). The respective amounts will be paid within 7 days from the date of withdrawal from the study to the study sponsor, The Bio-Forum Foundation, bank account at Banca Transilvania, SWIFT BTRLRO22, IBAN RO72BTRLRONCRT0056512501.

However, the decision of not continuing to participate in this study for whatever reason will not interfere with other medical care which I am reasonably expected to receive in the future.

No adverse effects were reported when administering this type of supplement at these doses.

Some patients have noticed a decrease in weight during the administration of this type of supplements as indicated (at least 30 minutes before meals).

By signing below I acknowledge that I was informed about the following:

1. Variants and alternatives of treatment (medicine, surgery, electromagnetic or chemical sclerosing of nodules, etc.), and the natural evolution of the benign thyroid nodules without treatment

2. Possible benefits and side effects (weight loss, allergic type reactions, including anaphylactic shock) as well as treatment needed in such situations (discontinuation of the supplement, administration of anti-histamine medication, epinephrine or cortisone-based treatment)

3. The necessary or recommended analyzes (imaging by thyroid ultrasound and laboratory tests done from blood samples harvested from the antecubital vein via venipuncture), the treatment stages, the duration of my participation in this study and the costs incurred on my part

I have understood the benefits and the risks of the administration of the treatment, I agree with the participation in the study in the above conditions, and I sign below:

Patient Name \_\_\_\_\_

Signature \_\_\_\_\_ Date of signature \_\_\_\_ / \_\_\_\_ / \_\_\_\_