Informed Consent Form

To Mr./Mrs. _____

ID no. _____, born in _____,

gender _____, home address _____

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You have been invited to participate in the study titled: *"Effects of photobiomodulation therapy in patients with chronic non-specific low back pain: a randomized placebo-controlled trial"*. This trial aims to evaluate the efficacy of photobiomodulation therapy (PBMT) in patients with non-specific chronic low back. In order to participate, you will be firstly screened by one of the researchers, who will determine if you are eligible for the study. If so, you will you respond a number of scales and questionnaires that measure intensity of your low back pain, disability, and impression of recovery since the onset of your symptoms. At the initial assessment, you will be asked to perform some movements of your spine and some tests will be carried out to better understand your clinical condition. You may feel some discomfort during and after the assessment, which tends to improve in the short term. The researchers involved in this study will take all necessary care to minimize these possible discomforts. After the assessment, you will be randomly allocated to two possible interventions: 1) active PBMT (therapy with a light with special properties capable of penetrating the tissues of your body and triggering therapeutic effects) or 2) placebo PBMT (therapy with a light having special properties capable of penetrating the tissues of your body and triggering therapeutic effects, applied at a very low dose below the therapeutic dose). You will not be able to identify which intervention you will be receiving. For safety reasons, during the application of the therapies, you must wear special, dark, protective goggles that will block the passage of light. This equipment will be provided by the therapist. Wearing these glasses will protect your eyes from direct contact with the light, thus avoiding possible damage to your eyesight. If you feel any discomfort during therapy, please notify the therapist and request immediate interruption of the application. In addition, regardless of the group to which you will be allocated, you will also receive an information booklet designed specifically for patients with low back pain (there are several studies that demonstrate the effectiveness of this booklet in patients with low back pain). In addition, you will be free to clarify any questions at each session with your therapist. The treatment will last 12 sessions (3 sessions weekly, for 4 weeks,

lasting 30 minutes each). After the end of treatment, you will be reassessed by the same therapist who evaluated you initially. This therapist will contact you at 3, 6, and 12 months after the beginning of the treatment to measure your symptoms.
Any clarifications can be provided by the chief investigator, Leonardo Oliveira Pena Costa, at Rua Cesário Galeno, 448, Tatuapé or via telephone on (11) 2178-1564.
We guarantee the confidentiality of all the information collected and you may withdraw your consent at any time, without any penalty or loss of benefit.

I hereby attest that I have been informed and fully understand the objectives of this study, the techniques and procedures I will receive, and the risks and discomforts that may occur. I have received guarantee of total confidentiality and of obtaining further clarification whenever I wish. Therefore, I agree to voluntarily participate in this study and I understand that I may withdraw my consent at any time without any penalty or loss of benefit (if the subject is enrolled in the Institution where the research is being conducted).

Date: __ / _ / __

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Signature of study participant or legal representative

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Chief investigator

I, Leonardo Oliveira Pena Costa, chief investigator of the study *"Effects of photobiomodulation therapy in patients with chronic non-specific low back pain: a randomized placebo-controlled trial"* hereby declare that I have obtained the free consent of this study participant (or his or her legal representative) to conduct this study.

Date: __ / __ / ___

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Signature of the chief investigator